

US3772037 (Prod: Paradigm Clinical Research Institute Inc - ClinEdge - PPDS)

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:16:06

All time stamps listed in this document are displayed in GMT

US3772037

Form: Participant Creation

Generated On: 26 Nov 2020 11:16:06

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:16:06

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	11 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:06

Date of Birth (MMM yyyy)	(b) (6) 1948
Age	72
Age Units	YEARS
Age (Derived)	72
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
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

Generated On: 26 Nov 2020 11:16:06

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 ☐
	Amendment 2 ☒
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:16:06

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:16:06

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:06

Condition	HYPOKALEMIA
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:06

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:06

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:06

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:16:06

Condition	NUEROPATHY (DUE TO RIGHT ANKLE FRACTURE) (SENSORY)
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:16:06

Condition	ASTHMA (MODERATE)
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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 (7)

Generated On: 26 Nov 2020 11:16:06

Condition	COMPLETE HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1992
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1992
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1992
Start Year (derived)	1992
Stop Month and Year (derived)	JAN 1992
Stop Year (derived)	1992

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:16:06

Condition	RIGHT ANKLE FRACTURE
Start date (dd MMM yyyy)	19 SEP 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	19 SEP 2012
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2012
Start Year (derived)	2012
Stop Month and Year (derived)	SEP 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	11 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:10 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 09:10
Height (<i>xxx.x</i>)	155 cm
Weight (<i>xxx.x</i>)	82 kg
BMI (<i>xxx.x</i>)	34.13111 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
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

Generated On: 26 Nov 2020 11:16:06

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

Generated On: 26 Nov 2020 11:16:06

Date of assessment (<i>dd MMM yyyy</i>)	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 (<i>dd MMM yyyy</i>)	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>)	UN UNK 1992
Date of last menstruation unknown	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:06

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

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:06

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

Generated On: 26 Nov 2020 11:16:06

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	11 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:06

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

What was the participant's randomization number? 185097

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

Generated On: 26 Nov 2020 11:16:06

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:06

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	11 AUG 2020
Time of assessment (00:00-23:59)	09:10 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 09:10
Temperature (xxx.x)	35.9 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:06

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	11 AUG 2020
Time of assessment (00:00-23:59)	10:40 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 10:40
Temperature (xxx.x)	36.7 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:06

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

Generated On: 26 Nov 2020 11:16:06

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) 10:04 (24 HR)

Treatment Date and Time (derived) 11 AUG 2020 10:04

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

Generated On: 26 Nov 2020 11:16:06

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	11 AUG 2020
Collection time (<i>00:00-23:59</i>)	09:38 (24 HR)
Collection date and time (derived)	11 AUG 2020 09:38

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:16:06

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	09:44	11 AUG 2020 09:44
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:16:06

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: 26 Nov 2020 11:16:06

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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 AUG 2020 10:43

PC Open Date & Time

11 AUG 2020 10:24

PC Close Date & Time

11 AUG 2020 12:54

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

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 98.0 °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	11 AUG 2020 18:32
PC Open Date & Time	11 AUG 2020 13:49
PC Close Date & Time	12 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:06

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

99.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 18:28

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes ☒
	No ☐
Please record your TEMPERATURE in °F	97.2 °F
Was any MEDICATION TAKEN today for pain or fever ?	Yes ☒
	No ☐

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

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

PC Time Stamp	13 AUG 2020 18:38
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 18:36

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:06

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

98.1 °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

15 AUG 2020 18:32

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:06

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

16 AUG 2020 19:08

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:06

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

17 AUG 2020 18:11

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

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

11 AUG 2020 10:47

PC Open Date & Time

11 AUG 2020 10:24

PC Close Date & Time

11 AUG 2020 12:54

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

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

11 AUG 2020 18:33

PC Open Date & Time

11 AUG 2020 13:49

PC Close Date & Time

12 AUG 2020 11:59

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:06

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 ☐

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

5

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

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 18:31

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:06

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)**

1

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

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 18:39

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:06

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

14 AUG 2020 18:36

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:06

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

15 AUG 2020 18:33

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:16:06

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

16 AUG 2020 19:09

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:06

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

17 AUG 2020 18:12

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 10:47
PC Open Date & Time	11 AUG 2020 10:24
PC Close Date & Time	11 AUG 2020 12:54

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 18:34
PC Open Date & Time	11 AUG 2020 13:49
PC Close Date & Time	12 AUG 2020 11:59

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:06

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 ☒

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:06

Yes ☐	
PC Time stamp	12 AUG 2020 18:32
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:06

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 ☒

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:06

Yes ☐	
PC Time stamp	13 AUG 2020 18:41
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:06

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 ☒

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:06

Yes ☐	
PC Time stamp	14 AUG 2020 18:37
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:06

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 ☒

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:06

Yes ☐	
PC Time stamp	15 AUG 2020 18:33
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:06

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 ☒

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:06

Yes ☐	
PC Time stamp	16 AUG 2020 19:09
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:06

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 ☒

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:06

Yes ☐	
PC Time stamp	17 AUG 2020 18:12
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3772037

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

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

PATIENT NOTIFIED ME THAT
SHE ACCIDENTALLY MARKED
HEADACHE AS A SYMPTOM ON
DAY 1. SO THIS IS A FALSE SIDE
EFFECT.

US3772037

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772037

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772037

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772037

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772037

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:06

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	08 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:06

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	08 SEP 2020
Time of assessment (00:00-23:59)	10:45 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 10:45
Temperature (xxx.x)	36.5 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:06

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	08 SEP 2020
Time of assessment (00:00-23:59)	11:59 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 11:59
Temperature (xxx.x)	36.5 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3772037

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:06

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.

US3772037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:06

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)	11:22 (24 HR)
Treatment Date and Time (derived)	08 SEP 2020 11:22
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

US3772037

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:06

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	08 SEP 2020
Collection time (<i>00:00-23:59</i>)	11:03 (24 HR)
Collection date and time (derived)	08 SEP 2020 11:03

US3772037

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:16:06

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	11:06	08 SEP 2020 11:06
Nasopharyngeal Swab 2	No		

US3772037

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

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 11:59

PC Open Date & Time 08 SEP 2020 11:42

PC Close Date & Time 08 SEP 2020 14:12

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

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 97.4 °F

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

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

PC Time Stamp	08 SEP 2020 17:50
PC Open Date & Time	08 SEP 2020 15:07
PC Close Date & Time	09 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:06

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

99.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 16:25

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:06

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

98.0 °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

10 SEP 2020 17:41

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:06

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 18:00

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 20:16

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 14:06

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 11:03

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

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 12:00

PC Open Date & Time

08 SEP 2020 11:42

PC Close Date & Time

08 SEP 2020 14:12

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

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 17:51

PC Open Date & Time

08 SEP 2020 15:07

PC Close Date & Time

09 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:06

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 ☐

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

1

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

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 16:26

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 17:42

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 18:01

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 20:17

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 14:06

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:06

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

15 SEP 2020 11:03

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 12:00
PC Open Date & Time	08 SEP 2020 11:42
PC Close Date & Time	08 SEP 2020 14:12

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 17:51
PC Open Date & Time	08 SEP 2020 15:07
PC Close Date & Time	09 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:06

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 ☒

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:06

Yes ☐	
PC Time stamp	09 SEP 2020 16:27
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:06

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 ☒

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:06

Yes ☐	
PC Time stamp	10 SEP 2020 17:42
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:06

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 ☒

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:06

Yes ☐	
PC Time stamp	11 SEP 2020 18:01
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:06

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 ☒

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:06

Yes ☐	
PC Time stamp	12 SEP 2020 20:17
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:06

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 ☒

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:06

Yes ☐	
PC Time stamp	13 SEP 2020 14:07
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:06

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 ☒

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:06

Yes ☐	
PC Time stamp	15 SEP 2020 11:03
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3772037

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772037

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772037

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772037

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:06

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	12 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3772037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	12 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	08:40 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 08:40
Temperature (<i>xxx.x</i>)	36.3 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	64 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	65 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3772037

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:06

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.

US3772037

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:06

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	12 OCT 2020
Collection time (<i>00:00-23:59</i>)	09:00 (24 HR)
Collection date and time (derived)	12 OCT 2020 09:00

US3772037

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 OCT 2020 07:42:55

Patient Cloud Open Date & Time

11 OCT 2020 00:01

Patient Cloud Close Date & Time

15 OCT 2020 23:59

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

18 OCT 2020 07:46:24

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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	25 OCT 2020 14:24:44
Patient Cloud Open Date & Time	25 OCT 2020 00:01
Patient Cloud Close Date & Time	29 OCT 2020 23:59

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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)	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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	08 NOV 2020 02:48:22
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

15 NOV 2020 10:28:08

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2020 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2020 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2020 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2020 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2020 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2020 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

22 NOV 2020 02:58:33

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2020 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2020 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2020 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2020 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

[Patient Cloud Close Date & Time](#)

18 JAN 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

DAY 194

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

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

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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22 FEB 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

[Patient Cloud Close Date & Time](#)

22 MAR 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

[Patient Cloud Close Date & Time](#)

05 APR 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐ Yes ☐

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐ Yes ☐

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

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17 JAN 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

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31 JAN 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

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07 FEB 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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Date and time of submission

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10 FEB 2022 00:01

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14 FEB 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

Date and time of submission

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17 FEB 2022 00:01

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21 FEB 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

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28 FEB 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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Date and time of submission

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US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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Date and time of submission

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US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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Date and time of submission

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21 MAR 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

Date and time of submission

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24 MAR 2022 00:01

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28 MAR 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

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04 APR 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

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11 APR 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Date and time of submission

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14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐ Yes ☐

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Date and time of submission

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21 APR 2022 00:01

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25 APR 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

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02 JUN 2022 00:01

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06 JUN 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐ Yes ☐

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

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09 JUN 2022 00:01

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13 JUN 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

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16 JUN 2022 00:01

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20 JUN 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

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27 JUN 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

DAY 691

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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04 JUL 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

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11 JUL 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

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21 JUL 2022 00:01

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25 JUL 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

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01 AUG 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3772037

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

Was Contact Attempted?

Yes ☒

No ☐

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

04 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772037

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772037

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:06

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:16:06

Date of Contact	13 NOV 2020
Time of Contact	14:00
Date and Time of Contact (derived)	13 NOV 2020 14:00
Type of Contact	Clinic Visit - Scheduled ☒
	Clinical Visit - Unscheduled ☐
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☒
	No ☐

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:16:06

Symptom Day

Day 1	☒
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:16:06

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	07 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	36.2 C	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	342 of 2190	

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:16:06

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:16:06

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:16:06

Symptom Day

Day 1	☐
Day 2	☒
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:16:06

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	14 NOV 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	346 of 2190	

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:16:06

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:16:06

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:16:06

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☒
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:16:06

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	16 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	350 of 2190	

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:16:06

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:16:06

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:16:06

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☒
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:16:06

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	15 NOV 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	354 of 2190	

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:16:06

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:16:06

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:16:06

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☒
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:16:06

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	17 NOV 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	36.5 C	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	358 of 2190	

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:16:06

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:16:06

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:16:06

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☒
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:16:06

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	18 NOV 2020	
Assessment Not Done	False	
O2 Saturation	91 %	
O2 Saturation Units	%	
Temperature	36.7 C	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	362 of 2190	

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:16:06

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:16:06

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:16:06

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☒
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:16:06

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	19 OCT 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	36.7 C	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	366 of 2190	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:16:06

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:16:06

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:16:06

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☒
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:16:06

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	20 NOV 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	370 of 2190	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:16:06

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:16:06

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:16:06

Date of Visit	13 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ☒ No ☐
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ☐ No ☒
Date of Test	11 NOV 2020
Type of Test Performed	Nasopharyngeal Swab ☒ Nasal Swab ☐ Saliva Test ☐ Other ☐
Other, specify _____	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☐ No ☒
If yes, provide lab information below	
Lab/ Institution Test Performed	_____
CLIA Certified?	Yes ☐ No ☐
COVID-19 Positive (CSA Programming Field Only)	0

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:16:06

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

US3772037

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 11:16:06

Visit	Was Saliva Collected?	Date of Collection
Day 3		
Day 5		
Day 7		
Day 9		
Day 14		
Day 21		
Day 28		

US3772037

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:06

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	13 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD1

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	13 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	14:15 (24 HR)
Vital Signs Date and Time (derived)	13 NOV 2020 14:15
Height (<i>xxx.x</i>)	ND - Not Done
Weight (<i>xxx.x</i>)	ND - Not Done
Temperature (<i>xxx.x</i>)	36.2 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	75 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3772037

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 NOV 2020

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

US3772037

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 11:16:06

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

13 NOV 2020

US3772037

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:06

Was this visit performed?	Yes ☐
	No ☐

Visit date (dd MMM yyyy)	

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

Folder OID	

US3772037

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:06

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.

US3772037

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 11:16:06

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

US3772037

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:16:06

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

AEID	USA-US107-2020-MRNA-1273-P30 1000002
Adverse event	ACUTE HYPOXIC RESPIRATORY FAILURE DUE TO COVID-19 INFECTION
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)	07 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	12 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	08 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	12 NOV 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

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 ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

SUBJECT WAS CONTACTED REGARDING SAFETY REPORT OF COVID EXPOSURE AND SYMPTOMS. THE SUBJECT REPORTED BEING TESTED FOR COVID ON THE SAME DAY THEY WERE DX WITH SINUSITIS (05 NOV 2020) AND RECEIVING A POSITIVE RESULT ON 07 NOV 2020. THE SUBJECT WAS ADVISED TO GO TO THE HOSPITAL IF THEIR OXYGEN SATURATION WAS BELOW 90. THE SUBJECT REPORTED HAVING AN O2 SATURATION OF 88 ON 8TH OF NOVEMBER. SELF REFERRED TO ER. THE SUBJECT WAS ADMITTED AS AN INPATIENT ON 08 NOV 2020. MEDICAL RECORDS HAVE BEEN REQUESTED FOR COVID TEST RESULTS AND HOSPITAL STAY.

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

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:16:06

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

Yes ☒

No ☐

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

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:06

Name of Medication	POTASSIUM CHLORIDE
Prophylaxis	Yes ☐ No ☒
Indication	KYPOKALEMIA
Dose per administration	20
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	MEQ
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 ☐ Intramuscular ☐

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:06

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2010
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:06

Name of Medication	ROSUVASTATIN
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 ☐ Intramuscular ☐

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:06

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Ongoing?	Yes ☒
	No ☐
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:06

Name of Medication	AMLODIPINE
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 ☐ Intramuscular ☐

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:06

Name of Medication	LEVOTHYROXINE
Prophylaxis	Yes ☐ No ☒
Indication	HYPOTHYROIDISM
Dose per administration	25
Dose unit	mg ☐ ug ☒ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:06

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Ongoing?	Yes ☒
	No ☐
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:06

Name of Medication	GABAPENTIN
Prophylaxis	Yes ☐ No ☒
Indication	NEUROPATHY (RIGHT ANKLE)
Dose per administration	100
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:06

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2014
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:16:06

Name of Medication	HYDROCHLOROTHIAZIDE
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
Dose per administration	25
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:16:06

Name of Medication	SYMBICORT
Prophylaxis	Yes ☐ No ☒
Indication	ASTHMA
Dose per administration	160/4.5
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 ☐ Intramuscular ☐

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:16:06

	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:06

Name of Medication	TYLENOL
Prophylaxis	Yes ☐ No ☒
Indication	PAIN AT INJECTION SITE
Dose per administration	500
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:06

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	13 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)		13 AUG 2020
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:16:06

Name of Medication	INFLUENZA VACCINATION
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 ☐
	Intramuscular ☒

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:16:06

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		27 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		27 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☐

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:16:06

Name of Medication	DEXAMETHASONE (DECADRON)
Prophylaxis	Yes ☐ No ☒
Indication	COVID-19
Dose per administration	6/1.5
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	MG/ML
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:16:06

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	07 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		12 NOV 2020
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:16:06

Name of Medication	CEFDINIR
Prophylaxis	Yes ☐ No ☒
Indication	SINUSITIS
Dose per administration	300
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:16:06

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		05 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		07 NOV 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:06

Name of Medication	ADVIL
Prophylaxis	Yes ☐ No ☒
Indication	SINUSITIS
Dose per administration	200
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 ☐ Intramuscular ☐

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:06

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	05 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ☒
If not Ongoing, End date (dd MMM yyyy)	05 NOV 2020
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:16:06

Name of Medication	DEXAMETHASONE
Prophylaxis	Yes ☐ No ☒
Indication	COVID-19
Dose per administration	6
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:16:06

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	13 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)	16 NOV 2020	
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	803 ☐
	804 ☒	

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:16:06

Name of Medication	SUPPLEMENTAL OXYGEN
Prophylaxis	Yes ☐ No ☒
Indication	COVID-19
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	LITER
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	CONTINUOUS
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:16:06

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☒
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	08 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	10 NOV 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:16:06

Name of Medication	DUONEB TREATMENT (IPRATROPIUM BROMIDE/ ALBUTEROL SULFATE)
Prophylaxis	Yes ☐ No ☒
Indication	COVID-19
Dose per administration	0.5/3/3
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	MG/MG/ML
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:16:06

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	07 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		07 NOV 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3772037

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:16:06

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3772037

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:16:06

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

US3772037

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:16:06

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 ☐

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

SAEID	USA-US107-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
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)	3

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:16:06

SAEID	USA-US107-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
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)	3
Date of submission (Pre-filled from custom function)	10/NOV/2020 10:42
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

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:16:06

SAEID	USA-US107-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
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)	3
Date of submission (Pre-filled from custom function)	17/NOV/2020 19:07
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

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:16:06

SAEID	USA-US107-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
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)	3
Date of submission (Pre-filled from custom function)	19/NOV/2020 11:10
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

US3772037 (Prod: Paradigm Clinical Research Institute Inc - ClinEdge - PPDS)

US3772037

Form: Participant Creation

Generated On: 26 Nov 2020 11:16:06

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3772037'	RWS_ENDPOINT ENDPOINT (b) (4) 	11 Aug 2020 16:04:42

US3772037

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:16:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:13:31

US3772037

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	11 Aug 2020 16:04:43

US3772037

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:13:31

US3772037

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:16:06

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	11 Aug 2020 17:13:31

US3772037

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered (b) (6) 1948'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	11 Aug 2020 16:04:44

US3772037

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:06

[Age](#)

Audit	User	Time (GMT)
User entered '72'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:13:48

US3772037

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:06

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	11 Aug 2020 17:13:48

US3772037

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:06

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '72'	System	11 Aug 2020 17:14:09

US3772037

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:06

Sex

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Recon: GCL recorded the sex as female; However, EDC records sex as male. Please reconcile. (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 18:27:39
Query 'Per GCL Lab Recon: GCL recorded the sex as female; However, EDC records sex as male. Please reconcile. answered with 'entry error updated' (Site from DM).	Emily Crews (b) (4) (b) (4)	26 Oct 2020 16:22:29
User entered 'Female (F)' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	26 Oct 2020 16:22:19
User opened query 'Per GCL Lab Recon: GCL recorded the sex as female; However, EDC records sex as male. Please reconcile. (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 01:55:05
User entered 'Male (M)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:13:48

US3772037

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:06

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:13:48

US3772037

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:06

[White](#)

Audit	User	Time (GMT)
User entered '1'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:13:48

US3772037

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:06

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:13:48

US3772037

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:06

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:13:48

US3772037

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:06

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:13:48

US3772037

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:06

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:13:48

US3772037

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:06

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:13:48

US3772037

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:06

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:13:48

US3772037

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:06

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:13:48

US3772037

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:06

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:13:48

US3772037

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:14:09

US3772037

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	11 Aug 2020 17:14:09

US3772037

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '2020'	System	11 Aug 2020 17:14:09

US3772037

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:06

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:14:09

US3772037

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:14:09

US3772037

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:14:09

US3772037

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:06

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:14:09

US3772037

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:06

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:14:09

US3772037

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:06

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	11 Aug 2020 16:04:43

US3772037

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:06

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 17:14:14

US3772037

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:14:14

US3772037

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:16:06

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:14:31

US3772037

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:06

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Potassium imbalance, PT: Hypokalaemia, LLT: Hypokalemia - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 17:15:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 17:15:19
Data point term sent to Coder	System	11 Aug 2020 17:14:59
User entered 'Hypokalemia'	Emily Crews (b) (4)	11 Aug 2020 17:14:56
	(b) (4)	

US3772037

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:14:56

US3772037

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:14:56

US3772037

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:14:56

US3772037

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:06

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:14:56

US3772037

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:14:56

US3772037

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	11 Aug 2020 17:14:56

US3772037

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '2010'	System	11 Aug 2020 17:14:56

US3772037

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 17:14:56

US3772037

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 17:14:56

US3772037

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:06

[Condition](#)

Audit	User	Time (GMT)
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)	11 Aug 2020 17:17:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 17:17:16
Data point term sent to Coder	System	11 Aug 2020 17:16:01
User entered 'Hyperlipidemia'	Emily Crews (b) (4)	11 Aug 2020 17:15:27

US3772037

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:15:27

US3772037

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:15:27

US3772037

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:15:27

US3772037

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:06

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:15:27

US3772037

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:15:27

US3772037

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	11 Aug 2020 17:15:27

US3772037

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '2010'	System	11 Aug 2020 17:15:27

US3772037

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 17:15:27

US3772037

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 17:15:27

US3772037

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:06

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4)	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)	11 Aug 2020 17:18:22
Data point term sent to Coder	System	11 Aug 2020 17:17:03
User entered 'Hypertension'	Emily Crews (b) (4)	11 Aug 2020 17:16:28

US3772037

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:16:28

US3772037

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:16:28

US3772037

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:16:28

US3772037

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:06

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:16:28

US3772037

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:16:28

US3772037

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	11 Aug 2020 17:16:28

US3772037

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '2010'	System	11 Aug 2020 17:16:28

US3772037

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 17:16:28

US3772037

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 17:16:28

US3772037

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:06

Condition

Audit	User	Time (GMT)
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)	11 Aug 2020 17:19:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 17:19:10
Data point term sent to Coder	System	11 Aug 2020 17:18:04
User entered 'Hypothyroidism'	Emily Crews (b) (4)	11 Aug 2020 17:17:40
	(b) (4)	

US3772037

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:17:40

US3772037

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:17:40

US3772037

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:17:40

US3772037

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:06

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:17:40

US3772037

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:17:40

US3772037

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	11 Aug 2020 17:17:40

US3772037

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '2010'	System	11 Aug 2020 17:17:40

US3772037

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 17:17:40

US3772037

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 17:17:40

US3772037

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:16:06

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Peripheral sensory neuropathy, LLT: Peripheral sensory neuropathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 08:17:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 08:17:05
User closed query 'Per DM CLR: Please verify the type of the NEUROPATHY (i.e. sensory or motor) and location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 23:38:03
Data point term sent to Coder	System	05 Nov 2020 22:34:14
Query 'Per DM CLR: Please verify the type of the NEUROPATHY (i.e. sensory or motor) and location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 22:34:08
User entered 'NUEROPATHY (DUE TO RIGHT ANKLE FRACTURE) (Sensory)' reason for change: Per Query Resolution	(b) (4), (b) (6)	05 Nov 2020 22:33:56
User opened query 'Per DM CLR: Please verify the type of the NEUROPATHY (i.e. sensory or motor) and location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 10:15:33
Data point term sent to Coder	System	15 Sep 2020 22:56:20
User closed query 'For coding purposes, please split NUEROPATHY DUE TO RIGHT ANKLE FRACTURE into separate entries. 1. RIGHT ANKLE FRACTURE and 2. NEUROPATHY [DUE TO RIGHT ANKLE FRACTURE]' (Site from System).	System	15 Sep 2020 22:55:57

US3772037

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:16:06

[Condition](#)

Audit	User	Time (GMT)
Query 'For coding purposes, please split NUEROPATHY DUE TO RIGHT ANKLE FRACTURE into separate entries. 1. RIGHT ANKLE FRACTURE and 2. NEUROPATHY [DUE TO RIGHT ANKLE FRACTURE]' answered with 'Updated confirmed via TC with subject' (Site from System).	Emily Crews (b) (4)	15 Sep 2020 22:55:57
Data point term sent to Coder	System	15 Sep 2020 22:52:12
User entered 'NUEROPATHY (DUE TO RIGHT ANKLE FRACTURE)' reason for change: Data Entry Error	Emily Crews (b) (4)	15 Sep 2020 22:51:11
User opened query 'For coding purposes, please split NUEROPATHY DUE TO RIGHT ANKLE FRACTURE into separate entries. 1. RIGHT ANKLE FRACTURE and 2. NEUROPATHY [DUE TO RIGHT ANKLE FRACTURE]' (Site from System).	Coder Import (b) (4)	31 Aug 2020 19:49:30
Data point term sent to Coder	System	11 Aug 2020 17:19:06
User entered 'Nueropathy due to right ankle fracture'	Emily Crews (b) (4)	11 Aug 2020 17:18:52

US3772037

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'un UNK 2014'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:18:52

US3772037

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:16:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:18:52

US3772037

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:16:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:18:52

US3772037

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:16:06

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:18:52

US3772037

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:16:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:18:52

US3772037

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	11 Aug 2020 17:18:52

US3772037

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '2014'	System	11 Aug 2020 17:18:52

US3772037

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 17:18:52

US3772037

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 17:18:52

US3772037

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:16:06

[Condition](#)

Audit	User	Time (GMT)
User closed query '22Oct2020(b) (6):Please confirm asthma severity. Thank you.' (Site from CRA).	(b) (4), (b) (6)	01 Nov 2020 23:53:36
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 16:54:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	26 Oct 2020 16:54:17
Data point term sent to Coder	System	26 Oct 2020 16:26:41
Query '22Oct2020(b) (6):Please confirm asthma severity. Thank you.' answered with 'updated' (Site from CRA).	Emily Crews (b) (4) (b) (4)	26 Oct 2020 16:25:51
Coding entries removed.	Emily Crews (b) (4) (b) (4)	26 Oct 2020 16:25:42
User entered 'ASTHMA (Moderate)' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	26 Oct 2020 16:25:42
User opened query '22Oct2020(b) (6):Please confirm asthma severity. Thank you.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 06:54:34
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:21:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 17:21:12
Data point term sent to Coder	System	11 Aug 2020 17:20:06
User entered 'Asthma'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:19:31

US3772037

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:19:31

US3772037

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:16:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:19:31

US3772037

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:16:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:19:31

US3772037

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:16:06

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:19:31

US3772037

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:16:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:19:31

US3772037

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	11 Aug 2020 17:19:31

US3772037

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '2015'	System	11 Aug 2020 17:19:31

US3772037

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 17:19:31

US3772037

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 17:19:31

US3772037

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:16:06

[Condition](#)

Audit	User	Time (GMT)
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) (b) (4)	17 Sep 2020 15:50:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 15:50:41
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:21:12
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 17:21:12
Data point term sent to Coder	System	11 Aug 2020 17:20:07
User entered 'Complete Hysterectomy'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:19:49

US3772037

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'un UNK 1992'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:19:49

US3772037

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:16:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:19:49

US3772037

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:16:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:19:49

US3772037

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:16:06

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'un UNK 1992'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:19:49

US3772037

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:16:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:19:49

US3772037

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'Jan 1992'	System	11 Aug 2020 17:19:49

US3772037

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '1992'	System	11 Aug 2020 17:19:49

US3772037

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'Jan 1992'	System	11 Aug 2020 17:19:49

US3772037

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '1992'	System	11 Aug 2020 17:19:49

US3772037

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:16:06

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Ankle fracture, LLT: Ankle fracture - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 22:57:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 22:57:54
Data point term sent to Coder	System	15 Sep 2020 22:56:17
User entered 'Right Ankle Fracture'	Emily Crews (b) (4)	15 Sep 2020 22:55:35
	(b) (4)	

US3772037

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '19 Sep 2012'	Emily Crews (b) (4) (b) (4)	15 Sep 2020 22:55:35

US3772037

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:16:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	15 Sep 2020 22:55:35

US3772037

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:16:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	15 Sep 2020 22:55:35

US3772037

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:16:06

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '19 Sep 2012'	Emily Crews (b) (4) (b) (4)	15 Sep 2020 22:55:35

US3772037

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:16:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	15 Sep 2020 22:55:35

US3772037

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'Sep 2012'	System	15 Sep 2020 22:55:35

US3772037

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '2012'	System	15 Sep 2020 22:55:35

US3772037

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'Sep 2012'	System	15 Sep 2020 22:55:35

US3772037

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '2012'	System	15 Sep 2020 22:55:35

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:20:37

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:20:37

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '09:10'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:20:37

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 09:10'	System	11 Aug 2020 17:20:37

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '155' cm	Emily Crews (b) (4)	11 Aug 2020 17:20:37
DataPoint set to visible.	(b) (4) System	11 Aug 2020 17:14:14

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '82' kg	Emily Crews (b) (4)	11 Aug 2020 17:20:37
DataPoint set to visible.	(b) (4) System	11 Aug 2020 17:14:14

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '34.13111'	System	16 Sep 2020 23:51:43
User entered '34.1'	System	11 Aug 2020 17:20:37
DataPoint set to visible.	System	11 Aug 2020 17:14:14

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	11 Aug 2020 17:20:37
DataPoint set to visible.	System	11 Aug 2020 17:14:14

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

Temperature (xxx.x)

Audit	User	Time (GMT)
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) (6)	16 Sep 2020 17:33:36
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)	15 Sep 2020 22:57:51
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4)	15 Sep 2020 22:57:38
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 11:50:50
User entered '35.9' C	Emily Crews (b) (4)	11 Aug 2020 17:20:37

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Emily Crews (b) (4)	15 Sep 2020 22:57:38
User entered 'Oral (Oral)'	Emily Crews (b) (4)	11 Aug 2020 17:20:37

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:20:37

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4)	15 Sep 2020 22:57:38
User entered '64'	Emily Crews (b) (4)	11 Aug 2020 17:20:37

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Aug 2020 17:20:37

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4)	15 Sep 2020 22:57:38
User entered '18'	Emily Crews (b) (4)	11 Aug 2020 17:20:37

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Aug 2020 17:20:37

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4)	15 Sep 2020 22:57:38
User entered '122'	Emily Crews (b) (4)	11 Aug 2020 17:20:37

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 17:20:37

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4)	15 Sep 2020 22:57:38
User entered '76'	Emily Crews (b) (4)	11 Aug 2020 17:20:37

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 17:20:37

US3772037

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:19

US3772037

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:06

[Date of examination \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 12:29:02
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		08 Sep 2020 18:08:17
User entered '11 Aug 2020'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:19

US3772037

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:16:06

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Emily Crews (b) (4) (b) (4)	26 Oct 2020 16:23:23

US3772037

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	26 Oct 2020 16:23:23

US3772037

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:16:06

[If No, what is the reason?](#)

Audit	User	Time (GMT)
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Emily Crews (b) (4) (b) (4)	26 Oct 2020 16:23:23

US3772037

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	26 Oct 2020 16:23:23

US3772037

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	26 Oct 2020 16:23:23

US3772037

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:16:06

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	26 Oct 2020 16:23:23

US3772037

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'un UNK 1992'	Emily Crews (b) (4) (b) (4)	26 Oct 2020 16:23:23

US3772037

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:16:06

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	26 Oct 2020 16:23:23

US3772037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

US3772037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

US3772037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

US3772037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

US3772037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

US3772037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

US3772037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

US3772037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

US3772037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

US3772037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

US3772037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

US3772037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:06

Other

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

US3772037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:06

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

US3772037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:06

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

US3772037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:06

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

US3772037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

US3772037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

US3772037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

US3772037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '1'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

US3772037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:06

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

US3772037

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:06

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

US3772037

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:16:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:22:20

US3772037

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:22:20

US3772037

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:22:20

US3772037

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:16:06

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	11 Aug 2020 17:22:20

US3772037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	11 Aug 2020 16:39:09

US3772037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:06

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:34:58
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:34:58
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 16:39:09
User entered '185097' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	11 Aug 2020 16:39:09

US3772037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) 	11 Aug 2020 16:39:09

US3772037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:22:40

US3772037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:22:40

US3772037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:22:40

US3772037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:22:40

US3772037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:06

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:22:40

US3772037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Oct 2020 21:06:58
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:17:35
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:31:07

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:16:06

Height

Audit	User	Time (GMT)
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) (6)	16 Sep 2020 15:50:01
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 'Updated' (Site from DM).	Emily Crews (b) (4)	15 Sep 2020 22:58:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4)	15 Sep 2020 22:58:14
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 11:51:17
User entered '155' cm	Emily Crews (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:16:06

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4)	15 Sep 2020 22:58:14
User entered '82' kg	Emily Crews (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:16:06

Height

Audit	User	Time (GMT)
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) (6)	16 Sep 2020 15:50:01
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.'	Emily Crews (b) (4)	15 Sep 2020 22:58:19
answered with 'Updated' (Site from DM).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4)	15 Sep 2020 22:58:14
	(b) (4)	
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 11:51:17
User entered '155' cm	Emily Crews (b) (4)	11 Aug 2020 17:23:56
	(b) (4)	

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:16:06

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4)	15 Sep 2020 22:58:14
User entered '82' kg	Emily Crews (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:06

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:06

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '09:10'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 09:10'	System	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:06

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 09:35:57
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.'	Emily Crews (b) (4)	18 Sep 2020 21:15:56
answered with 'NCS' (Site from System).	(b) (4)	
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:51:43
User entered '35.9' C	Emily Crews (b) (4)	11 Aug 2020 17:23:56
	(b) (4)	

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:06

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:06

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '64'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:06

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '18'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '122'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '76'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:16:06

Height

Audit	User	Time (GMT)
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) (6)	16 Sep 2020 15:50:01
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 'Updated' (Site from DM).	Emily Crews (b) (4)	15 Sep 2020 22:58:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4)	15 Sep 2020 22:58:14
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 11:51:17
User entered '155' cm	Emily Crews (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:16:06

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4)	15 Sep 2020 22:58:14
User entered '82' kg	Emily Crews (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:06

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 18:11:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 18:11:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Emily Crews (b) (4)	11 Aug 2020 18:11:28
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 17:23:56
User entered empty.	Emily Crews (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Aug 2020' reason for change: Data Entry Error	Emily Crews (b) (4)	11 Aug 2020 18:11:28
User entered empty.	Emily Crews (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
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) (6)	18 Aug 2020 13:38:08
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		11 Aug 2020 18:11:28
User entered '10:40' reason for change: Data Entry Error	Emily Crews (b) (4)	11 Aug 2020 18:11:28
User entered empty.	Emily Crews (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 10:40'	System	11 Aug 2020 18:11:28
User entered empty.	System	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:06

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.7' C reason for change: Data Entry Error	Emily Crews (b) (4)	11 Aug 2020 18:11:28
User entered empty.	Emily Crews (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:06

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	Emily Crews (b) (4)	11 Aug 2020 18:11:28
User entered empty.	Emily Crews (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:06

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '65' reason for change: Data Entry Error	Emily Crews (b) (4)	11 Aug 2020 18:11:28
User entered empty.	Emily Crews (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:06

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Aug 2020 18:11:28
User entered empty.	System	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '20' reason for change: Data Entry Error	Emily Crews (b) (4)	11 Aug 2020 18:11:28
User entered empty.	Emily Crews (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Aug 2020 18:11:28
User entered empty.	System	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '124' reason for change: Data Entry Error	Emily Crews (b) (4)	11 Aug 2020 18:11:28
User entered empty.	Emily Crews (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 18:11:28
User entered empty.	System	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '64' reason for change: Data Entry Error	Emily Crews (b) (4)	11 Aug 2020 18:11:28
User entered empty.	Emily Crews (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 18:11:28
User entered empty.	System	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:06

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:24:08

US3772037

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:24:08

US3772037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:08

US3772037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:06

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:08

US3772037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:08

US3772037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:06

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 17:21:08

US3772037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:06

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:08

US3772037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '10:04'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:08

US3772037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 10:04'	System	11 Aug 2020 17:21:08

US3772037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 19:07:16
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 18:33:34
User entered 'Left Arm (LEFT ARM)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:08

US3772037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	11 Aug 2020 17:21:08

US3772037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:06

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 17:21:08

US3772037

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:24:21

US3772037

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:24:21

US3772037

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '09:38'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:24:21

US3772037

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 09:38'	System	11 Aug 2020 17:24:21

US3772037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:24:33

US3772037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:16:06

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:24:33

US3772037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:16:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:24:33

US3772037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:16:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '09:44'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:24:33

US3772037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 09:44'	System	11 Aug 2020 17:24:33

US3772037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:16:06

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:24:33

US3772037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:16:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:24:33

US3772037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:24:33

US3772037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 17:24:33

US3772037

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:24:38

US3772037

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:16:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 17:24:38

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T10:42:32', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8187e5e3-7b4b-408e-9f44-19768cf95576'	System	11 Aug 2020 17:43:11
User entered 'Yes (Y)'	System	11 Aug 2020 17:43:11

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T10:42:40', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8187e5e3-7b4b-408e-9f44-19768cf95576'	System	11 Aug 2020 17:43:11
User entered '98.1'	System	11 Aug 2020 17:43:11

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T10:43:01', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8187e5e3-7b4b-408e-9f44-19768cf95576'	System	11 Aug 2020 17:43:11
User entered 'No (N)'	System	11 Aug 2020 17:43:11

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T10:43:07', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8187e5e3-7b4b-408e-9f44-19768cf95576'	System	11 Aug 2020 17:43:11
User entered '11 Aug 2020 10:43'	System	11 Aug 2020 17:43:11

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 10:24'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:54'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T18:32:41', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'd97cf25e-8e41-43ea-92d2-20225e33b246'	System	12 Aug 2020 01:33:03
User entered 'Yes (Y)'	System	12 Aug 2020 01:33:03

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T18:32:47', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'd97cf25e-8e41-43ea-92d2-20225e33b246'	System	12 Aug 2020 01:33:03
User entered '98.0'	System	12 Aug 2020 01:33:03

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T18:32:51', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'd97cf25e-8e41-43ea-92d2-20225e33b246'	System	12 Aug 2020 01:33:03
User entered 'No (N)'	System	12 Aug 2020 01:33:03

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T18:32:58', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'd97cf25e-8e41-43ea-92d2-20225e33b246'	System	12 Aug 2020 01:33:03
User entered '11 Aug 2020 18:32'	System	12 Aug 2020 01:33:03

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 13:49'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 2'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:27:49', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '7149b014-193a-4a94-90c7-274f68620a7a'	System	13 Aug 2020 01:28:09
User entered 'Yes (Y)'	System	13 Aug 2020 01:28:09

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:27:57', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '7149b014-193a-4a94-90c7-274f68620a7a'	System	13 Aug 2020 01:28:09
User entered '99.4'	System	13 Aug 2020 01:28:09

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:28:02', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '7149b014-193a-4a94-90c7-274f68620a7a'	System	13 Aug 2020 01:28:09
User entered 'No (N)'	System	13 Aug 2020 01:28:09

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:28:08', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '7149b014-193a-4a94-90c7-274f68620a7a'	System	13 Aug 2020 01:28:09
User entered '12 Aug 2020 18:28'	System	13 Aug 2020 01:28:09

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 3'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:37:49', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '0f71d1e9-07a9-4d30-bad2-e329ed89a775'	System	14 Aug 2020 01:38:39
User entered 'Yes (Y)'	System	14 Aug 2020 01:38:39

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:37:55', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '0f71d1e9-07a9-4d30-bad2-e329ed89a775'	System	14 Aug 2020 01:38:39
User entered '97.2'	System	14 Aug 2020 01:38:39

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:38:12', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '0f71d1e9-07a9-4d30-bad2-e329ed89a775'	System	14 Aug 2020 01:38:39
User entered 'Yes (Y)'	System	14 Aug 2020 01:38:39

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 17:47:34
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Confirmed with subject, conmed updated ' (Site from System).	Emily Crews (b) (4)	14 Aug 2020 15:44:43
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	14 Aug 2020 01:38:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:38:32', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '0f71d1e9-07a9-4d30-bad2-e329ed89a775'	System	14 Aug 2020 01:38:39
User entered '1'	System	14 Aug 2020 01:38:39

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:06

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:38:32', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '0f71d1e9-07a9-4d30-bad2-e329ed89a775'	System	14 Aug 2020 01:38:39
User entered '0'	System	14 Aug 2020 01:38:39

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:38:37', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '0f71d1e9-07a9-4d30-bad2-e329ed89a775'	System	14 Aug 2020 01:38:39
User entered '13 Aug 2020 18:38'	System	14 Aug 2020 01:38:39

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 4'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-14T18:36:24', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'bfb1edd0-b2c2-43a1-bcdd-eb9eba6eb7d4'	System	15 Aug 2020 01:36:30
User entered 'Yes (Y)'	System	15 Aug 2020 01:36:30

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-14T18:36:17', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'bfb1edd0-b2c2-43a1-bcdd-eb9eba6eb7d4'	System	15 Aug 2020 01:36:30
User entered '97.5'	System	15 Aug 2020 01:36:30

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-14T18:36:20', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'bfb1edd0-b2c2-43a1-bcdd-eb9eba6eb7d4'	System	15 Aug 2020 01:36:30
User entered 'No (N)'	System	15 Aug 2020 01:36:30

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-14T18:36:26', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'bfb1edd0-b2c2-43a1-bcdd-eb9eba6eb7d4'	System	15 Aug 2020 01:36:30
User entered '14 Aug 2020 18:36'	System	15 Aug 2020 01:36:30

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 5'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-15T18:32:33', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '96ddd206-29a4-474a-8f1d-08f379d882f6'	System	16 Aug 2020 01:32:51
User entered 'Yes (Y)'	System	16 Aug 2020 01:32:51

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-15T18:32:38', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '96ddd206-29a4-474a-8f1d-08f379d882f6'	System	16 Aug 2020 01:32:51
User entered '98.1'	System	16 Aug 2020 01:32:51

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-15T18:32:43', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '96ddd206-29a4-474a-8f1d-08f379d882f6'	System	16 Aug 2020 01:32:51
User entered 'No (N)'	System	16 Aug 2020 01:32:51

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-15T18:32:49', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '96ddd206-29a4-474a-8f1d-08f379d882f6'	System	16 Aug 2020 01:32:51
User entered '15 Aug 2020 18:32'	System	16 Aug 2020 01:32:51

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 6'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-16T19:08:34', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '98e86745-d53f-4eeb-a877-e5626e380881'	System	17 Aug 2020 02:08:49
User entered 'Yes (Y)'	System	17 Aug 2020 02:08:49

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-16T19:08:38', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '98e86745-d53f-4eeb-a877-e5626e380881'	System	17 Aug 2020 02:08:49
User entered '98.1'	System	17 Aug 2020 02:08:49

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-16T19:08:41', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '98e86745-d53f-4eeb-a877-e5626e380881'	System	17 Aug 2020 02:08:49
User entered 'No (N)'	System	17 Aug 2020 02:08:49

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-16T19:08:45', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '98e86745-d53f-4eeb-a877-e5626e380881'	System	17 Aug 2020 02:08:49
User entered '16 Aug 2020 19:08'	System	17 Aug 2020 02:08:49

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 7'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-17T18:11:33', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '7f48d62d-5871-4621-a6a6-882e48f89e5d'	System	18 Aug 2020 01:11:47
User entered 'Yes (Y)'	System	18 Aug 2020 01:11:47

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-17T18:11:37', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '7f48d62d-5871-4621-a6a6-882e48f89e5d'	System	18 Aug 2020 01:11:47
User entered '98.0'	System	18 Aug 2020 01:11:47

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-17T18:11:40', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '7f48d62d-5871-4621-a6a6-882e48f89e5d'	System	18 Aug 2020 01:11:47
User entered 'No (N)'	System	18 Aug 2020 01:11:47

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-17T18:11:44', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '7f48d62d-5871-4621-a6a6-882e48f89e5d'	System	18 Aug 2020 01:11:47
User entered '17 Aug 2020 18:11'	System	18 Aug 2020 01:11:47

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T10:46:28', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '89bca285-e94b-4cf8-9326-32191a454ee7'	System	11 Aug 2020 17:47:05
User entered 'Any use of prescription pain reliever or System prevents daily activity (4)'		11 Aug 2020 17:47:05

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T10:46:38', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '89bca285-e94b-4cf8-9326-32191a454ee7'	System	11 Aug 2020 17:47:05
User entered 'No (N)'	System	11 Aug 2020 17:47:05

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T10:46:46', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '89bca285-e94b-4cf8-9326-32191a454ee7'	System	11 Aug 2020 17:47:05
User entered 'No (N)'	System	11 Aug 2020 17:47:05

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T10:46:57', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '89bca285-e94b-4cf8-9326-32191a454ee7'	System	11 Aug 2020 17:47:05
User entered 'Any use of prescription pain reliever or System prevents daily activity (4)'		11 Aug 2020 17:47:05

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T10:47:01', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '89bca285-e94b-4cf8-9326-32191a454ee7'	System	11 Aug 2020 17:47:05
User entered '11 Aug 2020 10:47'	System	11 Aug 2020 17:47:05

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 10:24'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:54'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T18:33:10', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8a6955f7-af73-4c7f-95c6-d74165b3ab82'	System	12 Aug 2020 01:33:34
User entered 'Does not interfere with activity (2)'	System	12 Aug 2020 01:33:34

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T18:33:16', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8a6955f7-af73-4c7f-95c6-d74165b3ab82'	System	12 Aug 2020 01:33:34
User entered 'No (N)'	System	12 Aug 2020 01:33:34

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T18:33:23', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8a6955f7-af73-4c7f-95c6-d74165b3ab82'	System	12 Aug 2020 01:33:34
User entered 'No (N)'	System	12 Aug 2020 01:33:34

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T18:33:29', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8a6955f7-af73-4c7f-95c6-d74165b3ab82'	System	12 Aug 2020 01:33:34
User entered 'None (1)'	System	12 Aug 2020 01:33:34

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T18:33:32', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8a6955f7-af73-4c7f-95c6-d74165b3ab82'	System	12 Aug 2020 01:33:34
User entered '11 Aug 2020 18:33'	System	12 Aug 2020 01:33:34

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 13:49'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 2'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:06

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:28:17', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5d9a970d-9ae7-48ea-84bc-844187136e07'	System	13 Aug 2020 01:31:53
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 01:31:53

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:29:02', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5d9a970d-9ae7-48ea-84bc-844187136e07'	System	13 Aug 2020 01:31:53
User entered 'Yes (Y)'	System	13 Aug 2020 01:31:53

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:06

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:31:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5d9a970d-9ae7-48ea-84bc-844187136e07'	System	13 Aug 2020 01:31:53
User entered '5'	System	13 Aug 2020 01:31:53

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:31:19', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5d9a970d-9ae7-48ea-84bc-844187136e07'	System	13 Aug 2020 01:31:53
User entered 'No (N)'	System	13 Aug 2020 01:31:53

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:06

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:31:44', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5d9a970d-9ae7-48ea-84bc-844187136e07'	System	13 Aug 2020 01:31:53
User entered 'None (1)'	System	13 Aug 2020 01:31:53

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:31:50', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5d9a970d-9ae7-48ea-84bc-844187136e07'	System	13 Aug 2020 01:31:53
User entered '12 Aug 2020 18:31'	System	13 Aug 2020 01:31:53

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 3'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:06

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:38:50', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'e0d889f2-8181-4557-82d1-294b20ec745d'	System	14 Aug 2020 01:39:48
User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 01:39:48

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:39:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'e0d889f2-8181-4557-82d1-294b20ec745d'	System	14 Aug 2020 01:39:48
User entered 'Yes (Y)'	System	14 Aug 2020 01:39:48

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:06

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:39:15', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'e0d889f2-8181-4557-82d1-294b20ec745d' User entered '1'	System	14 Aug 2020 01:39:48

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:39:37', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'e0d889f2-8181-4557-82d1-294b20ec745d'	System	14 Aug 2020 01:39:48
User entered 'No (N)'	System	14 Aug 2020 01:39:48

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:06

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:39:43', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'e0d889f2-8181-4557-82d1-294b20ec745d'	System	14 Aug 2020 01:39:48
User entered 'None (1)'	System	14 Aug 2020 01:39:48

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:39:45', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'e0d889f2-8181-4557-82d1-294b20ec745d'	System	14 Aug 2020 01:39:48
User entered '13 Aug 2020 18:39'	System	14 Aug 2020 01:39:48

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 4'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:06

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-14T18:36:31', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '67da81af-5eda-4458-81b2-ac03f4b15038'	System	15 Aug 2020 01:36:49
User entered 'None (1)'	System	15 Aug 2020 01:36:49

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-14T18:36:35', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '67da81af-5eda-4458-81b2-ac03f4b15038'	System	15 Aug 2020 01:36:49
User entered 'No (N)'	System	15 Aug 2020 01:36:49

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-14T18:36:41', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '67da81af-5eda-4458-81b2-ac03f4b15038'	System	15 Aug 2020 01:36:49
User entered 'No (N)'	System	15 Aug 2020 01:36:49

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:06

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-14T18:36:43', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '67da81af-5eda-4458-81b2-ac03f4b15038'	System	15 Aug 2020 01:36:49
User entered 'None (1)'	System	15 Aug 2020 01:36:49

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-14T18:36:45', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '67da81af-5eda-4458-81b2-ac03f4b15038'	System	15 Aug 2020 01:36:49
User entered '14 Aug 2020 18:36'	System	15 Aug 2020 01:36:49

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 5'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:06

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-15T18:33:06', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '1e05e102-bf42-4c77-8191-b9542c2aea82'	System	16 Aug 2020 01:33:26
User entered 'None (1)'	System	16 Aug 2020 01:33:26

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-15T18:33:08', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '1e05e102-bf42-4c77-8191-b9542c2aea82'	System	16 Aug 2020 01:33:26
User entered 'No (N)'	System	16 Aug 2020 01:33:26

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-15T18:33:13', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '1e05e102-bf42-4c77-8191-b9542c2aea82'	System	16 Aug 2020 01:33:26
User entered 'No (N)'	System	16 Aug 2020 01:33:26

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:06

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-15T18:33:19', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '1e05e102-bf42-4c77-8191-b9542c2aea82'	System	16 Aug 2020 01:33:26
User entered 'None (1)'	System	16 Aug 2020 01:33:26

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-15T18:33:23', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '1e05e102-bf42-4c77-8191-b9542c2aea82'	System	16 Aug 2020 01:33:26
User entered '15 Aug 2020 18:33'	System	16 Aug 2020 01:33:26

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 6'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:16:06

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-16T19:08:49', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '4009f9ce-9e7b-4717-9a4d-d2c446de0084'	System	17 Aug 2020 02:09:01
User entered 'None (1)'	System	17 Aug 2020 02:09:01

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-16T19:08:52', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '4009f9ce-9e7b-4717-9a4d-d2c446de0084'	System	17 Aug 2020 02:09:01
User entered 'No (N)'	System	17 Aug 2020 02:09:01

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-16T19:08:54', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '4009f9ce-9e7b-4717-9a4d-d2c446de0084'	System	17 Aug 2020 02:09:01
User entered 'No (N)'	System	17 Aug 2020 02:09:01

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:16:06

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-16T19:08:57', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '4009f9ce-9e7b-4717-9a4d-d2c446de0084'	System	17 Aug 2020 02:09:01
User entered 'None (1)'	System	17 Aug 2020 02:09:01

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:16:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-16T19:09:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '4009f9ce-9e7b-4717-9a4d-d2c446de0084'	System	17 Aug 2020 02:09:01
User entered '16 Aug 2020 19:09'	System	17 Aug 2020 02:09:01

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 7'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:06

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-17T18:11:58', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'd583b0f9-3b0f-4c22-8205-6da4140202f0'	System	18 Aug 2020 01:12:15
User entered 'None (1)'	System	18 Aug 2020 01:12:15

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-17T18:12:01', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'd583b0f9-3b0f-4c22-8205-6da4140202f0'	System	18 Aug 2020 01:12:15
User entered 'No (N)'	System	18 Aug 2020 01:12:15

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-17T18:12:08', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'd583b0f9-3b0f-4c22-8205-6da4140202f0'	System	18 Aug 2020 01:12:15
User entered 'No (N)'	System	18 Aug 2020 01:12:15

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:06

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-17T18:12:10', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'd583b0f9-3b0f-4c22-8205-6da4140202f0'	System	18 Aug 2020 01:12:15
User entered 'None (1)'	System	18 Aug 2020 01:12:15

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-17T18:12:12', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'd583b0f9-3b0f-4c22-8205-6da4140202f0'	System	18 Aug 2020 01:12:15
User entered '17 Aug 2020 18:12'	System	18 Aug 2020 01:12:15

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T10:47:17', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'eaf24b65-c0a8-4f24-aa93-9045501253bd'	System	11 Aug 2020 17:47:58
User entered 'Any use of prescription pain reliever or prevents daily activity (3)'	System	11 Aug 2020 17:47:58

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T10:47:31', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'eaf24b65-c0a8-4f24-aa93-9045501253bd'	System	11 Aug 2020 17:47:58
User entered 'None (0)'	System	11 Aug 2020 17:47:58

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T10:47:34', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'eaf24b65-c0a8-4f24-aa93-9045501253bd' User entered 'None (0)'	System	11 Aug 2020 17:47:58
	System	11 Aug 2020 17:47:58

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T10:47:38', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'eaf24b65-c0a8-4f24-aa93-9045501253bd' User entered 'None (0)'	System	11 Aug 2020 17:47:58
	System	11 Aug 2020 17:47:58

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T10:47:42', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'eaf24b65-c0a8-4f24-aa93-9045501253bd'	System	11 Aug 2020 17:47:58
User entered 'None (0)'	System	11 Aug 2020 17:47:58

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T10:47:44', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'eaf24b65-c0a8-4f24-aa93-9045501253bd'	System	11 Aug 2020 17:47:58
User entered 'None (0)'	System	11 Aug 2020 17:47:58

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T10:47:51', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'eaf24b65-c0a8-4f24-aa93-9045501253bd'	System	11 Aug 2020 17:47:58
User entered 'No (N)'	System	11 Aug 2020 17:47:58

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T10:47:54', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'eaf24b65-c0a8-4f24-aa93-9045501253bd' User entered '11 Aug 2020 10:47'	System	11 Aug 2020 17:47:58
	System	11 Aug 2020 17:47:58

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 10:24'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:54'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T18:33:49', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '413fd8c1-3a31-4d5d-a3fa-b70edba76157'	System	12 Aug 2020 01:34:19
User entered 'None (0)'	System	12 Aug 2020 01:34:19

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T18:33:52', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '413fd8c1-3a31-4d5d-a3fa-b70edba76157'	System	12 Aug 2020 01:34:19
User entered 'None (0)'	System	12 Aug 2020 01:34:19

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T18:33:57', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '413fd8c1-3a31-4d5d-a3fa-b70edba76157'	System	12 Aug 2020 01:34:19
User entered 'None (0)'	System	12 Aug 2020 01:34:19

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T18:34:02', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '413fd8c1-3a31-4d5d-a3fa-b70edba76157'	System	12 Aug 2020 01:34:19
User entered 'None (0)'	System	12 Aug 2020 01:34:19

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T18:34:05', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '413fd8c1-3a31-4d5d-a3fa-b70edba76157'	System	12 Aug 2020 01:34:19
User entered 'None (0)'	System	12 Aug 2020 01:34:19

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T18:34:08', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '413fd8c1-3a31-4d5d-a3fa-b70edba76157'	System	12 Aug 2020 01:34:19
User entered 'None (0)'	System	12 Aug 2020 01:34:19

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T18:34:11', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '413fd8c1-3a31-4d5d-a3fa-b70edba76157'	System	12 Aug 2020 01:34:19
User entered 'No (N)'	System	12 Aug 2020 01:34:19

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T18:34:14', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '413fd8c1-3a31-4d5d-a3fa-b70edba76157'	System	12 Aug 2020 01:34:19
User entered '11 Aug 2020 18:34'	System	12 Aug 2020 01:34:19

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 13:49'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 2'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:31:56', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '750f0f6d-ae0b-4799-91f3-4e935eabc59c'	System	13 Aug 2020 01:32:16
User entered 'None (0)'	System	13 Aug 2020 01:32:16

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:31:58', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '750f0f6d-ae0b-4799-91f3-4e935eabc59c'	System	13 Aug 2020 01:32:16
User entered 'None (0)'	System	13 Aug 2020 01:32:16

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:32:01', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '750f0f6d-ae0b-4799-91f3-4e935eabc59c'	System	13 Aug 2020 01:32:16
User entered 'None (0)'	System	13 Aug 2020 01:32:16

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:32:03', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '750f0f6d-ae0b-4799-91f3-4e935eabc59c'	System	13 Aug 2020 01:32:16
User entered 'None (0)'	System	13 Aug 2020 01:32:16

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:32:05', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '750f0f6d-ae0b-4799-91f3-4e935eabc59c'	System	13 Aug 2020 01:32:16
User entered 'None (0)'	System	13 Aug 2020 01:32:16

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:32:07', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '750f0f6d-ae0b-4799-91f3-4e935eabc59c'	System	13 Aug 2020 01:32:16
User entered 'None (0)'	System	13 Aug 2020 01:32:16

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:32:10', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '750f0f6d-ae0b-4799-91f3-4e935eabc59c'	System	13 Aug 2020 01:32:16
User entered 'No (N)'	System	13 Aug 2020 01:32:16

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:32:13', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '750f0f6d-ae0b-4799-91f3-4e935eabc59c'	System	13 Aug 2020 01:32:16
User entered '12 Aug 2020 18:32'	System	13 Aug 2020 01:32:16

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 3'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:40:01', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '97253077-d432-49c4-8530-0cf41b40e17a'	System	14 Aug 2020 01:41:18
User entered 'None (0)'	System	14 Aug 2020 01:41:18

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:40:23', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '97253077-d432-49c4-8530-0cf41b40e17a'	System	14 Aug 2020 01:41:18
User entered 'None (0)'	System	14 Aug 2020 01:41:18

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:40:27', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '97253077-d432-49c4-8530-0cf41b40e17a'	System	14 Aug 2020 01:41:18
User entered 'None (0)'	System	14 Aug 2020 01:41:18

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:40:32', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '97253077-d432-49c4-8530-0cf41b40e17a'	System	14 Aug 2020 01:41:18
User entered 'None (0)'	System	14 Aug 2020 01:41:18

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:40:35', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '97253077-d432-49c4-8530-0cf41b40e17a'	System	14 Aug 2020 01:41:18
User entered 'None (0)'	System	14 Aug 2020 01:41:18

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:40:37', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '97253077-d432-49c4-8530-0cf41b40e17a'	System	14 Aug 2020 01:41:18
User entered 'None (0)'	System	14 Aug 2020 01:41:18

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:40:56', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '97253077-d432-49c4-8530-0cf41b40e17a'	System	14 Aug 2020 01:41:18
User entered 'No (N)'	System	14 Aug 2020 01:41:18

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:41:16', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '97253077-d432-49c4-8530-0cf41b40e17a'	System	14 Aug 2020 01:41:18
User entered '13 Aug 2020 18:41'	System	14 Aug 2020 01:41:18

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:06

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 4'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-14T18:36:50', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8dbb22f0-1a54-4185-a4a6-c12100b2990c'	System	15 Aug 2020 01:37:08
User entered 'None (0)'	System	15 Aug 2020 01:37:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-14T18:36:52', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8dbb22f0-1a54-4185-a4a6-c12100b2990c'	System	15 Aug 2020 01:37:08
User entered 'None (0)'	System	15 Aug 2020 01:37:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-14T18:36:54', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8dbb22f0-1a54-4185-a4a6-c12100b2990c'	System	15 Aug 2020 01:37:08
User entered 'None (0)'	System	15 Aug 2020 01:37:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-14T18:36:57', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8dbb22f0-1a54-4185-a4a6-c12100b2990c'	System	15 Aug 2020 01:37:08
User entered 'None (0)'	System	15 Aug 2020 01:37:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-14T18:36:59', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8dbb22f0-1a54-4185-a4a6-c12100b2990c'	System	15 Aug 2020 01:37:08
User entered 'None (0)'	System	15 Aug 2020 01:37:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-14T18:37:01', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8dbb22f0-1a54-4185-a4a6-c12100b2990c'	System	15 Aug 2020 01:37:08
User entered 'None (0)'	System	15 Aug 2020 01:37:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-14T18:37:03', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8dbb22f0-1a54-4185-a4a6-c12100b2990c'	System	15 Aug 2020 01:37:08
User entered 'No (N)'	System	15 Aug 2020 01:37:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-14T18:37:05', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8dbb22f0-1a54-4185-a4a6-c12100b2990c'	System	15 Aug 2020 01:37:08
User entered '14 Aug 2020 18:37'	System	15 Aug 2020 01:37:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 5'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-15T18:33:26', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'fc98d6b8-4e53-4e41-a2e0-f68584d21bfe'	System	16 Aug 2020 01:33:47
User entered 'None (0)'	System	16 Aug 2020 01:33:47

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-15T18:33:29', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'fc98d6b8-4e53-4e41-a2e0-f68584d21bfe'	System	16 Aug 2020 01:33:47
User entered 'None (0)'	System	16 Aug 2020 01:33:47

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-15T18:33:31', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'fc98d6b8-4e53-4e41-a2e0-f68584d21bfe'	System	16 Aug 2020 01:33:47
User entered 'None (0)'	System	16 Aug 2020 01:33:47

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-15T18:33:33', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'fc98d6b8-4e53-4e41-a2e0-f68584d21bfe'	System	16 Aug 2020 01:33:47
User entered 'None (0)'	System	16 Aug 2020 01:33:47

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-15T18:33:35', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'fc98d6b8-4e53-4e41-a2e0-f68584d21bfe'	System	16 Aug 2020 01:33:47
User entered 'None (0)'	System	16 Aug 2020 01:33:47

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-15T18:33:39', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'fc98d6b8-4e53-4e41-a2e0-f68584d21bfe'	System	16 Aug 2020 01:33:47
User entered 'None (0)'	System	16 Aug 2020 01:33:47

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-15T18:33:42', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'fc98d6b8-4e53-4e41-a2e0-f68584d21bfe'	System	16 Aug 2020 01:33:47
User entered 'No (N)'	System	16 Aug 2020 01:33:47

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-15T18:33:44', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'fc98d6b8-4e53-4e41-a2e0-f68584d21bfe'	System	16 Aug 2020 01:33:47
User entered '15 Aug 2020 18:33'	System	16 Aug 2020 01:33:47

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 6'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-16T19:09:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'b01b564f-d3b5-4617-abe2-ff6348f78859'	System	17 Aug 2020 02:09:27
User entered 'None (0)'	System	17 Aug 2020 02:09:27

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-16T19:09:06', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'b01b564f-d3b5-4617-abe2-ff6348f78859'	System	17 Aug 2020 02:09:27
User entered 'None (0)'	System	17 Aug 2020 02:09:27

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-16T19:09:08', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'b01b564f-d3b5-4617-abe2-ff6348f78859'	System	17 Aug 2020 02:09:27
User entered 'None (0)'	System	17 Aug 2020 02:09:27

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-16T19:09:11', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'b01b564f-d3b5-4617-abe2-ff6348f78859'	System	17 Aug 2020 02:09:27
User entered 'None (0)'	System	17 Aug 2020 02:09:27

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-16T19:09:14', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'b01b564f-d3b5-4617-abe2-ff6348f78859'	System	17 Aug 2020 02:09:27
User entered 'None (0)'	System	17 Aug 2020 02:09:27

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-16T19:09:16', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'b01b564f-d3b5-4617-abe2-ff6348f78859'	System	17 Aug 2020 02:09:27
User entered 'None (0)'	System	17 Aug 2020 02:09:27

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-16T19:09:21', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'b01b564f-d3b5-4617-abe2-ff6348f78859'	System	17 Aug 2020 02:09:27
User entered 'No (N)'	System	17 Aug 2020 02:09:27

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-16T19:09:23', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'b01b564f-d3b5-4617-abe2-ff6348f78859'	System	17 Aug 2020 02:09:27
User entered '16 Aug 2020 19:09'	System	17 Aug 2020 02:09:27

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 7'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-17T18:12:17', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9f024b29-7841-435b-bcc3-a51ba5304452'	System	18 Aug 2020 01:12:58
User entered 'None (0)'	System	18 Aug 2020 01:12:58

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-17T18:12:19', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9f024b29-7841-435b-bcc3-a51ba5304452'	System	18 Aug 2020 01:12:58
User entered 'None (0)'	System	18 Aug 2020 01:12:58

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-17T18:12:33', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9f024b29-7841-435b-bcc3-a51ba5304452'	System	18 Aug 2020 01:12:58
User entered 'None (0)'	System	18 Aug 2020 01:12:58

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-17T18:12:35', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9f024b29-7841-435b-bcc3-a51ba5304452'	System	18 Aug 2020 01:12:58
User entered 'None (0)'	System	18 Aug 2020 01:12:58

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-17T18:12:37', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9f024b29-7841-435b-bcc3-a51ba5304452'	System	18 Aug 2020 01:12:58
User entered 'None (0)'	System	18 Aug 2020 01:12:58

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-17T18:12:42', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9f024b29-7841-435b-bcc3-a51ba5304452'	System	18 Aug 2020 01:12:58
User entered 'None (0)'	System	18 Aug 2020 01:12:58

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-17T18:12:51', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9f024b29-7841-435b-bcc3-a51ba5304452'	System	18 Aug 2020 01:12:58
User entered 'No (N)'	System	18 Aug 2020 01:12:58

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-17T18:12:54', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9f024b29-7841-435b-bcc3-a51ba5304452'	System	18 Aug 2020 01:12:58
User entered '17 Aug 2020 18:12'	System	18 Aug 2020 01:12:58

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 18:41:02

US3772037

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '18 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 18:41:02

US3772037

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	18 Aug 2020 18:41:02

US3772037

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'Patient notified me that she accidentally marked headache as a symptom on Day 1. So this is a false side effect.'	(b) (4), (b) (6)	18 Aug 2020 18:41:02

US3772037

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 18:41:08

US3772037

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 18:41:08

US3772037

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	08 Sep 2020 17:59:35

US3772037

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020'	Emily Crews (b) (4) (b) (4)	08 Sep 2020 17:59:35

US3772037

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Emily Crews (b) (4) (b) (4)	08 Sep 2020 17:59:35

US3772037

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	08 Sep 2020 17:59:35

US3772037

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	08 Sep 2020 17:59:42

US3772037

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 17:59:42

US3772037

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	08 Sep 2020 18:00:29

US3772037

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020'	Emily Crews (b) (4) (b) (4)	08 Sep 2020 18:00:29

US3772037

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Emily Crews (b) (4) (b) (4)	08 Sep 2020 18:00:29

US3772037

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	08 Sep 2020 18:00:29

US3772037

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	08 Sep 2020 18:00:36

US3772037

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 18:00:36

US3772037

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:08:17

US3772037

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '08 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 18:08:17

US3772037

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Sep 2020 18:08:17

US3772037

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:06

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	08 Sep 2020 18:08:17

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:06

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:06

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '10:45'	(b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '08 Sep 2020 10:45'	System	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:06

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 21:20:54
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 21:20:54
User entered '36.5' C reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	08 Sep 2020 21:20:54
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 18:09:35
User entered empty.	(b) (4), (b) (6) (b) (4)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:06

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	Emily Crews (b) (4)	08 Sep 2020 21:20:54
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:06

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 21:20:54
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 21:20:54
User entered '72' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	08 Sep 2020 21:20:54
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 18:09:35
User entered empty.	(b) (4), (b) (6) (b) (4)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:06

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Sep 2020 21:20:54
User entered empty.	System	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 21:20:54
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 21:20:54
User entered '18' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	08 Sep 2020 21:20:54
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 18:09:35
User entered empty.	(b) (4), (b) (6) (b) (4)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Sep 2020 21:20:54
User entered empty.	System	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 21:20:54
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 21:20:54
User entered '128' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	08 Sep 2020 21:20:54
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 18:09:35
User entered empty.	(b) (4), (b) (6) (b) (4)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Sep 2020 21:20:54
User entered empty.	System	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 21:20:54
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 21:20:54
User entered '62' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	08 Sep 2020 21:20:54
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 18:09:35
User entered empty.	(b) (4), (b) (6) (b) (4)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Sep 2020 21:20:54
User entered empty.	System	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:06

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Emily Crews (b) (4)	08 Sep 2020 21:20:54
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Sep 2020' reason for change: Data Entry Error	Emily Crews (b) (4)	08 Sep 2020 21:20:54
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '11:59' reason for change: Data Entry Error	Emily Crews (b) (4)	08 Sep 2020 21:20:54
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	08 Sep 2020 21:20:54
User entered empty.	System	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:06

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.5' C reason for change: Data Entry Error	Emily Crews (b) (4)	08 Sep 2020 21:20:54
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:06

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	Emily Crews (b) (4)	08 Sep 2020 21:20:54
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:06

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '66' reason for change: Data Entry Error	Emily Crews (b) (4)	08 Sep 2020 21:20:54
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:06

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Sep 2020 21:20:54
User entered empty.	System	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '16' reason for change: Data Entry Error	Emily Crews (b) (4)	08 Sep 2020 21:20:54
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Sep 2020 21:20:54
User entered empty.	System	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '119' reason for change: Data Entry Error	Emily Crews (b) (4)	08 Sep 2020 21:20:54
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Sep 2020 21:20:54
User entered empty.	System	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '76' reason for change: Data Entry Error	Emily Crews (b) (4)	08 Sep 2020 21:20:54
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Sep 2020 21:20:54
User entered empty.	System	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:10:32

US3772037

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '08 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 18:10:32

US3772037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:32:40

US3772037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:06

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:32:40

US3772037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:32:40

US3772037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:06

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 18:32:40

US3772037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:06

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '08 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 18:32:40

US3772037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '11:22'	(b) (4), (b) (6)	08 Sep 2020 18:32:40

US3772037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:22'	System	08 Sep 2020 18:32:40

US3772037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	08 Sep 2020 19:07:16
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System).	System	08 Sep 2020 19:07:16
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	08 Sep 2020 19:07:01
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 19:07:01
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	08 Sep 2020 18:33:34
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System).	System	08 Sep 2020 18:33:34
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	08 Sep 2020 18:32:52
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 18:32:52
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	08 Sep 2020 18:32:40

US3772037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	08 Sep 2020 18:32:40

US3772037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:06

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 18:32:40

US3772037

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:33:55

US3772037

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '08 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 18:33:55

US3772037

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '11:03'	(b) (4), (b) (6)	08 Sep 2020 18:33:55

US3772037

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:03'	System	08 Sep 2020 18:33:55

US3772037

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '08 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 18:34:12

US3772037

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:16:06

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	08 Sep 2020 18:34:12

US3772037

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:16:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:34:12

US3772037

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '11:06'	(b) (4), (b) (6)	08 Sep 2020 18:34:12

US3772037

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:06'	System	08 Sep 2020 18:34:12

US3772037

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:16:06

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	08 Sep 2020 18:34:12

US3772037

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:16:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 18:34:12

US3772037

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:34:12

US3772037

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 18:34:12

US3772037

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:31:55

US3772037

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 20:31:55

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T11:59:32', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '588670b5-ed8c-44f2-9b7c-6a290f9d8cd9'	System	08 Sep 2020 18:59:47
User entered 'Yes (Y)'	System	08 Sep 2020 18:59:47

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T11:59:36', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '588670b5-ed8c-44f2-9b7c-6a290f9d8cd9' User entered '97.7'	System	08 Sep 2020 18:59:47

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T11:59:39', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '588670b5-ed8c-44f2-9b7c-6a290f9d8cd9'	System	08 Sep 2020 18:59:47
User entered 'No (N)'	System	08 Sep 2020 18:59:47

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T11:59:44', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '588670b5-ed8c-44f2-9b7c-6a290f9d8cd9'	System	08 Sep 2020 18:59:47
User entered '08 Sep 2020 11:59'	System	08 Sep 2020 18:59:47

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:42'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 14:12'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T17:50:49', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '87e098ac-b111-4657-9c2f-9e51ec5155c2'	System	09 Sep 2020 00:51:03
User entered 'Yes (Y)'	System	09 Sep 2020 00:51:03

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T17:50:53', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '87e098ac-b111-4657-9c2f-9e51ec5155c2'	System	09 Sep 2020 00:51:03
User entered '97.4'	System	09 Sep 2020 00:51:03

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T17:50:56', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '87e098ac-b111-4657-9c2f-9e51ec5155c2'	System	09 Sep 2020 00:51:03
User entered 'No (N)'	System	09 Sep 2020 00:51:03

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T17:50:59', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '87e098ac-b111-4657-9c2f-9e51ec5155c2'	System	09 Sep 2020 00:51:03
User entered '08 Sep 2020 17:50'	System	09 Sep 2020 00:51:03

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 15:07'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 2'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:24:09', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8c40974c-1aef-41ee-a298-1e814153cdbf'	System	09 Sep 2020 23:25:05
User entered 'Yes (Y)'	System	09 Sep 2020 23:25:05

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:24:53', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8c40974c-1aef-41ee-a298-1e814153cdbf'	System	09 Sep 2020 23:25:05
User entered '99.4'	System	09 Sep 2020 23:25:05

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:24:56', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8c40974c-1aef-41ee-a298-1e814153cdbf'	System	09 Sep 2020 23:25:05
User entered 'No (N)'	System	09 Sep 2020 23:25:05

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:25:01', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8c40974c-1aef-41ee-a298-1e814153cdbf'	System	09 Sep 2020 23:25:05
User entered '09 Sep 2020 16:25'	System	09 Sep 2020 23:25:05

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 3'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-10T17:40:45', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '2c2c8043-b50e-4fd1-aa26-9ae25268834f'	System	11 Sep 2020 00:41:04
User entered 'Yes (Y)'	System	11 Sep 2020 00:41:04

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-10T17:40:51', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '2c2c8043-b50e-4fd1-aa26-9ae25268834f'	System	11 Sep 2020 00:41:04
User entered '98.0'	System	11 Sep 2020 00:41:04

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-10T17:40:56', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '2c2c8043-b50e-4fd1-aa26-9ae25268834f'	System	11 Sep 2020 00:41:04
User entered 'No (N)'	System	11 Sep 2020 00:41:04

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-10T17:41:01', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '2c2c8043-b50e-4fd1-aa26-9ae25268834f'	System	11 Sep 2020 00:41:04
User entered '10 Sep 2020 17:41'	System	11 Sep 2020 00:41:04

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 4'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-11T18:00:36', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5ed6cd60-57e1-48c1-8355-17453b2bb371'	System	12 Sep 2020 01:00:53
User entered 'Yes (Y)'	System	12 Sep 2020 01:00:53

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-11T18:00:41', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5ed6cd60-57e1-48c1-8355-17453b2bb371'	System	12 Sep 2020 01:00:53
User entered '98.1'	System	12 Sep 2020 01:00:53

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-11T18:00:44', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5ed6cd60-57e1-48c1-8355-17453b2bb371'	System	12 Sep 2020 01:00:53
User entered 'No (N)'	System	12 Sep 2020 01:00:53

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-11T18:00:47', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5ed6cd60-57e1-48c1-8355-17453b2bb371'	System	12 Sep 2020 01:00:53
User entered '11 Sep 2020 18:00'	System	12 Sep 2020 01:00:53

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 5'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-12T20:16:18', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '7d4584e2-2d0b-42ce-8c10-73926a28b261'	System	13 Sep 2020 03:16:32
User entered 'Yes (Y)'	System	13 Sep 2020 03:16:32

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-12T20:16:23', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '7d4584e2-2d0b-42ce-8c10-73926a28b261'	System	13 Sep 2020 03:16:32
User entered '98.5'	System	13 Sep 2020 03:16:32

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-12T20:16:26', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '7d4584e2-2d0b-42ce-8c10-73926a28b261'	System	13 Sep 2020 03:16:32
User entered 'No (N)'	System	13 Sep 2020 03:16:32

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-12T20:16:29', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '7d4584e2-2d0b-42ce-8c10-73926a28b261'	System	13 Sep 2020 03:16:32
User entered '12 Sep 2020 20:16'	System	13 Sep 2020 03:16:32

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 6'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-13T14:06:20', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'a98981a6-4486-4182-b63d-0edc3edd1970'	System	13 Sep 2020 21:06:45
User entered 'Yes (Y)'	System	13 Sep 2020 21:06:45

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-13T14:06:24', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'a98981a6-4486-4182-b63d-0edc3edd1970'	System	13 Sep 2020 21:06:45
User entered '98.5'	System	13 Sep 2020 21:06:45

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-13T14:06:27', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'a98981a6-4486-4182-b63d-0edc3edd1970'	System	13 Sep 2020 21:06:45
User entered 'No (N)'	System	13 Sep 2020 21:06:45

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-13T14:06:30', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'a98981a6-4486-4182-b63d-0edc3edd1970'	System	13 Sep 2020 21:06:45
User entered '13 Sep 2020 14:06'	System	13 Sep 2020 21:06:45

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 7'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-15T11:02:58', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '74081002-eff3-452b-a0ee-0df27c18ef37'	System	15 Sep 2020 18:03:10
User entered 'Yes (Y)'	System	15 Sep 2020 18:03:10

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-15T11:03:03', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '74081002-eff3-452b-a0ee-0df27c18ef37'	System	15 Sep 2020 18:03:10
User entered '98.2'	System	15 Sep 2020 18:03:10

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-15T11:03:06', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '74081002-eff3-452b-a0ee-0df27c18ef37'	System	15 Sep 2020 18:03:10
User entered 'No (N)'	System	15 Sep 2020 18:03:10

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-15T11:03:08', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '74081002-eff3-452b-a0ee-0df27c18ef37'	System	15 Sep 2020 18:03:10
User entered '15 Sep 2020 11:03'	System	15 Sep 2020 18:03:10

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T11:59:51', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'f05de605-353d-4364-a9c5-5f42f40f7c0d'	System	08 Sep 2020 19:00:11
User entered 'None (1)'	System	08 Sep 2020 19:00:11

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T11:59:56', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'f05de605-353d-4364-a9c5-5f42f40f7c0d'	System	08 Sep 2020 19:00:11
User entered 'No (N)'	System	08 Sep 2020 19:00:11

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T12:00:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'f05de605-353d-4364-a9c5-5f42f40f7c0d'	System	08 Sep 2020 19:00:11
User entered 'No (N)'	System	08 Sep 2020 19:00:11

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T12:00:05', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'f05de605-353d-4364-a9c5-5f42f40f7c0d'	System	08 Sep 2020 19:00:11
User entered 'None (1)'	System	08 Sep 2020 19:00:11

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T12:00:08', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'f05de605-353d-4364-a9c5-5f42f40f7c0d'	System	08 Sep 2020 19:00:11
User entered '08 Sep 2020 12:00'	System	08 Sep 2020 19:00:11

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:42'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 14:12'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T17:51:07', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '52d22e7f-6d3d-44e8-b6d8-fd833c1bf46e'	System	09 Sep 2020 00:51:25
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 00:51:25

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T17:51:10', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '52d22e7f-6d3d-44e8-b6d8-fd833c1bf46e'	System	09 Sep 2020 00:51:25
User entered 'No (N)'	System	09 Sep 2020 00:51:25

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T17:51:16', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '52d22e7f-6d3d-44e8-b6d8-fd833c1bf46e'	System	09 Sep 2020 00:51:25
User entered 'No (N)'	System	09 Sep 2020 00:51:25

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T17:51:21', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '52d22e7f-6d3d-44e8-b6d8-fd833c1bf46e'	System	09 Sep 2020 00:51:25
User entered 'None (1)'	System	09 Sep 2020 00:51:25

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T17:51:23', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '52d22e7f-6d3d-44e8-b6d8-fd833c1bf46e'	System	09 Sep 2020 00:51:25
User entered '08 Sep 2020 17:51'	System	09 Sep 2020 00:51:25

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 15:07'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 2'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:06

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:25:11', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9e95cf29-2030-40ad-a7ed-8b1509bd5d5e'	System	09 Sep 2020 23:26:52
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 23:26:52

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:25:36', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9e95cf29-2030-40ad-a7ed-8b1509bd5d5e'	System	09 Sep 2020 23:26:52
User entered 'Yes (Y)'	System	09 Sep 2020 23:26:52

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:06

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:26:35', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9e95cf29-2030-40ad-a7ed-8b1509bd5d5e' User entered '1'	System	09 Sep 2020 23:26:52
	System	09 Sep 2020 23:26:52

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:26:40', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9e95cf29-2030-40ad-a7ed-8b1509bd5d5e'	System	09 Sep 2020 23:26:52
User entered 'No (N)'	System	09 Sep 2020 23:26:52

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:06

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:26:45', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9e95cf29-2030-40ad-a7ed-8b1509bd5d5e'	System	09 Sep 2020 23:26:52
User entered 'None (1)'	System	09 Sep 2020 23:26:52

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:26:48', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9e95cf29-2030-40ad-a7ed-8b1509bd5d5e'	System	09 Sep 2020 23:26:52
User entered '09 Sep 2020 16:26'	System	09 Sep 2020 23:26:52

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 3'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:06

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-10T17:41:11', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'a6e87769-b3a7-44cd-ad46-af774c98ef9a'	System	11 Sep 2020 00:42:06
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 00:42:06

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-10T17:41:13', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'a6e87769-b3a7-44cd-ad46-af774c98ef9a'	System	11 Sep 2020 00:42:06
User entered 'No (N)'	System	11 Sep 2020 00:42:06

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-10T17:41:20', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'a6e87769-b3a7-44cd-ad46-af774c98ef9a'	System	11 Sep 2020 00:42:06
User entered 'No (N)'	System	11 Sep 2020 00:42:06

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:06

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-10T17:41:36', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'a6e87769-b3a7-44cd-ad46-af774c98ef9a'	System	11 Sep 2020 00:42:06
User entered 'None (1)'	System	11 Sep 2020 00:42:06

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-10T17:42:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'a6e87769-b3a7-44cd-ad46-af774c98ef9a'	System	11 Sep 2020 00:42:06
User entered '10 Sep 2020 17:42'	System	11 Sep 2020 00:42:06

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 4'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:06

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-11T18:00:57', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '974794f0-f562-4506-83ab-06660e3a015e'	System	12 Sep 2020 01:01:16
User entered 'None (1)'	System	12 Sep 2020 01:01:16

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-11T18:01:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '974794f0-f562-4506-83ab-06660e3a015e'	System	12 Sep 2020 01:01:16
User entered 'No (N)'	System	12 Sep 2020 01:01:16

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-11T18:01:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '974794f0-f562-4506-83ab-06660e3a015e'	System	12 Sep 2020 01:01:16
User entered 'No (N)'	System	12 Sep 2020 01:01:16

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:06

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-11T18:01:07', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '974794f0-f562-4506-83ab-06660e3a015e'	System	12 Sep 2020 01:01:16
User entered 'None (1)'	System	12 Sep 2020 01:01:16

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-11T18:01:10', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '974794f0-f562-4506-83ab-06660e3a015e'	System	12 Sep 2020 01:01:16
User entered '11 Sep 2020 18:01'	System	12 Sep 2020 01:01:16

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 5'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:06

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-12T20:16:37', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'ac3bcf8a-ee11-4c63-92f1-31f82340f3ec'	System	13 Sep 2020 03:17:14
User entered 'None (1)'	System	13 Sep 2020 03:17:14

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-12T20:17:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'ac3bcf8a-ee11-4c63-92f1-31f82340f3ec'	System	13 Sep 2020 03:17:14
User entered 'No (N)'	System	13 Sep 2020 03:17:14

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-12T20:17:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'ac3bcf8a-ee11-4c63-92f1-31f82340f3ec'	System	13 Sep 2020 03:17:14
User entered 'No (N)'	System	13 Sep 2020 03:17:14

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:06

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-12T20:17:09', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'ac3bcf8a-ee11-4c63-92f1-31f82340f3ec'	System	13 Sep 2020 03:17:14
User entered 'None (1)'	System	13 Sep 2020 03:17:14

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-12T20:17:13', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'ac3bcf8a-ee11-4c63-92f1-31f82340f3ec'	System	13 Sep 2020 03:17:14
User entered '12 Sep 2020 20:17'	System	13 Sep 2020 03:17:14

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 6'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:16:06

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-13T14:06:36', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'c0fa5c6c-ba8a-4390-9b27-c953d3482ad8'	System	13 Sep 2020 21:07:03
User entered 'None (1)'	System	13 Sep 2020 21:07:03

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-13T14:06:39', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'c0fa5c6c-ba8a-4390-9b27-c953d3482ad8'	System	13 Sep 2020 21:07:03
User entered 'No (N)'	System	13 Sep 2020 21:07:03

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-13T14:06:45', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'c0fa5c6c-ba8a-4390-9b27-c953d3482ad8'	System	13 Sep 2020 21:07:03
User entered 'No (N)'	System	13 Sep 2020 21:07:03

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:16:06

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-13T14:06:55', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'c0fa5c6c-ba8a-4390-9b27-c953d3482ad8'	System	13 Sep 2020 21:07:03
User entered 'None (1)'	System	13 Sep 2020 21:07:03

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:16:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-13T14:06:58', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'c0fa5c6c-ba8a-4390-9b27-c953d3482ad8'	System	13 Sep 2020 21:07:03
User entered '13 Sep 2020 14:06'	System	13 Sep 2020 21:07:03

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 7'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:06

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-15T11:03:15', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'bc1e3cb4-cc82-4bfc-b680-6c5d1c27bbef'	System	15 Sep 2020 18:03:37
User entered 'None (1)'	System	15 Sep 2020 18:03:37

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-15T11:03:21', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'bc1e3cb4-cc82-4bfc-b680-6c5d1c27bbef'	System	15 Sep 2020 18:03:37
User entered 'No (N)'	System	15 Sep 2020 18:03:37

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-15T11:03:27', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'bc1e3cb4-cc82-4bfc-b680-6c5d1c27bbef'	System	15 Sep 2020 18:03:37
User entered 'No (N)'	System	15 Sep 2020 18:03:37

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:06

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-15T11:03:30', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'bc1e3cb4-cc82-4bfc-b680-6c5d1c27bbef'	System	15 Sep 2020 18:03:37
User entered 'None (1)'	System	15 Sep 2020 18:03:37

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-15T11:03:32', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'bc1e3cb4-cc82-4bfc-b680-6c5d1c27bbef'	System	15 Sep 2020 18:03:37
User entered '15 Sep 2020 11:03'	System	15 Sep 2020 18:03:37

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T12:00:13', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '12a0b870-b409-4de9-90aa-c08a1522fa74'	System	08 Sep 2020 19:00:40
User entered 'None (0)'	System	08 Sep 2020 19:00:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T12:00:17', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '12a0b870-b409-4de9-90aa-c08a1522fa74'	System	08 Sep 2020 19:00:40
User entered 'None (0)'	System	08 Sep 2020 19:00:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T12:00:20', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '12a0b870-b409-4de9-90aa-c08a1522fa74'	System	08 Sep 2020 19:00:40
User entered 'None (0)'	System	08 Sep 2020 19:00:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T12:00:22', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '12a0b870-b409-4de9-90aa-c08a1522fa74'	System	08 Sep 2020 19:00:40
User entered 'None (0)'	System	08 Sep 2020 19:00:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T12:00:25', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '12a0b870-b409-4de9-90aa-c08a1522fa74'	System	08 Sep 2020 19:00:40
User entered 'None (0)'	System	08 Sep 2020 19:00:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T12:00:28', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '12a0b870-b409-4de9-90aa-c08a1522fa74'	System	08 Sep 2020 19:00:40
User entered 'None (0)'	System	08 Sep 2020 19:00:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T12:00:30', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '12a0b870-b409-4de9-90aa-c08a1522fa74'	System	08 Sep 2020 19:00:40
User entered 'No (N)'	System	08 Sep 2020 19:00:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T12:00:33', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '12a0b870-b409-4de9-90aa-c08a1522fa74'	System	08 Sep 2020 19:00:40
User entered '08 Sep 2020 12:00'	System	08 Sep 2020 19:00:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:42'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 14:12'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T17:51:28', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'dde5e35f-66eb-43ea-a5e2-706462506ae0'	System	09 Sep 2020 00:51:49
User entered 'None (0)'	System	09 Sep 2020 00:51:49

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T17:51:32', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'dde5e35f-66eb-43ea-a5e2-706462506ae0'	System	09 Sep 2020 00:51:49
User entered 'None (0)'	System	09 Sep 2020 00:51:49

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T17:51:34', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'dde5e35f-66eb-43ea-a5e2-706462506ae0'	System	09 Sep 2020 00:51:49
User entered 'None (0)'	System	09 Sep 2020 00:51:49

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T17:51:37', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'dde5e35f-66eb-43ea-a5e2-706462506ae0'	System	09 Sep 2020 00:51:49
User entered 'None (0)'	System	09 Sep 2020 00:51:49

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T17:51:39', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'dde5e35f-66eb-43ea-a5e2-706462506ae0'	System	09 Sep 2020 00:51:49
User entered 'None (0)'	System	09 Sep 2020 00:51:49

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T17:51:43', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'dde5e35f-66eb-43ea-a5e2-706462506ae0'	System	09 Sep 2020 00:51:49
User entered 'None (0)'	System	09 Sep 2020 00:51:49

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T17:51:46', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'dde5e35f-66eb-43ea-a5e2-706462506ae0'	System	09 Sep 2020 00:51:49
User entered 'No (N)'	System	09 Sep 2020 00:51:49

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T17:51:48', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'dde5e35f-66eb-43ea-a5e2-706462506ae0'	System	09 Sep 2020 00:51:49
User entered '08 Sep 2020 17:51'	System	09 Sep 2020 00:51:49

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 15:07'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 2'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:26:58', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '71eaf7c2-8b57-45ec-8d0c-0b16bcea11e7'	System	09 Sep 2020 23:27:47
User entered 'None (0)'	System	09 Sep 2020 23:27:47

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:27:01', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '71eaf7c2-8b57-45ec-8d0c-0b16bcea11e7'	System	09 Sep 2020 23:27:47
User entered 'None (0)'	System	09 Sep 2020 23:27:47

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:27:10', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '71eaf7c2-8b57-45ec-8d0c-0b16bcea11e7'	System	09 Sep 2020 23:27:47
User entered 'None (0)'	System	09 Sep 2020 23:27:47

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:27:21', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '71eaf7c2-8b57-45ec-8d0c-0b16bcea11e7'	System	09 Sep 2020 23:27:47
User entered 'None (0)'	System	09 Sep 2020 23:27:47

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:27:24', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '71eaf7c2-8b57-45ec-8d0c-0b16bcea11e7'	System	09 Sep 2020 23:27:47
User entered 'None (0)'	System	09 Sep 2020 23:27:47

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:27:26', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '71eaf7c2-8b57-45ec-8d0c-0b16bcea11e7'	System	09 Sep 2020 23:27:47
User entered 'None (0)'	System	09 Sep 2020 23:27:47

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:27:41', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '71eaf7c2-8b57-45ec-8d0c-0b16bcea11e7'	System	09 Sep 2020 23:27:47
User entered 'No (N)'	System	09 Sep 2020 23:27:47

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:27:45', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '71eaf7c2-8b57-45ec-8d0c-0b16bcea11e7'	System	09 Sep 2020 23:27:47
User entered '09 Sep 2020 16:27'	System	09 Sep 2020 23:27:47

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 3'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-10T17:42:09', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '1c6599df-367a-4f42-a284-3175ad1a7628'	System	11 Sep 2020 00:42:37
User entered 'None (0)'	System	11 Sep 2020 00:42:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-10T17:42:12', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '1c6599df-367a-4f42-a284-3175ad1a7628'	System	11 Sep 2020 00:42:37
User entered 'None (0)'	System	11 Sep 2020 00:42:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-10T17:42:17', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '1c6599df-367a-4f42-a284-3175ad1a7628'	System	11 Sep 2020 00:42:37
User entered 'None (0)'	System	11 Sep 2020 00:42:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-10T17:42:24', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '1c6599df-367a-4f42-a284-3175ad1a7628'	System	11 Sep 2020 00:42:37
User entered 'None (0)'	System	11 Sep 2020 00:42:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-10T17:42:26', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '1c6599df-367a-4f42-a284-3175ad1a7628'	System	11 Sep 2020 00:42:37
User entered 'None (0)'	System	11 Sep 2020 00:42:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-10T17:42:29', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '1c6599df-367a-4f42-a284-3175ad1a7628'	System	11 Sep 2020 00:42:37
User entered 'None (0)'	System	11 Sep 2020 00:42:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-10T17:42:32', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '1c6599df-367a-4f42-a284-3175ad1a7628'	System	11 Sep 2020 00:42:37
User entered 'No (N)'	System	11 Sep 2020 00:42:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-10T17:42:35', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '1c6599df-367a-4f42-a284-3175ad1a7628'	System	11 Sep 2020 00:42:37
User entered '10 Sep 2020 17:42'	System	11 Sep 2020 00:42:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 4'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-11T18:01:15', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '6ad8f966-39b7-4c9f-ba97-f16b945fc1df' User entered 'None (0)'	System	12 Sep 2020 01:01:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-11T18:01:17', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '6ad8f966-39b7-4c9f-ba97-f16b945fc1df' User entered 'None (0)'	System	12 Sep 2020 01:01:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-11T18:01:19', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '6ad8f966-39b7-4c9f-ba97-f16b945fc1df' User entered 'None (0)'	System	12 Sep 2020 01:01:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-11T18:01:22', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '6ad8f966-39b7-4c9f-ba97-f16b945fc1df' User entered 'None (0)'	System	12 Sep 2020 01:01:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-11T18:01:24', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '6ad8f966-39b7-4c9f-ba97-f16b945fc1df'	System	12 Sep 2020 01:01:37
User entered 'None (0)'	System	12 Sep 2020 01:01:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-11T18:01:26', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '6ad8f966-39b7-4c9f-ba97-f16b945fc1df' User entered 'None (0)'	System	12 Sep 2020 01:01:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-11T18:01:28', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '6ad8f966-39b7-4c9f-ba97-f16b945fc1df' User entered 'No (N)'	System	12 Sep 2020 01:01:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-11T18:01:30', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '6ad8f966-39b7-4c9f-ba97-f16b945fc1df'	System	12 Sep 2020 01:01:37
User entered '11 Sep 2020 18:01'	System	12 Sep 2020 01:01:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 5'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-12T20:17:17', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'e04ee3c8-57f1-4d06-ba32-648fa0949cc4'	System	13 Sep 2020 03:17:37
User entered 'None (0)'	System	13 Sep 2020 03:17:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-12T20:17:20', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'e04ee3c8-57f1-4d06-ba32-648fa0949cc4'	System	13 Sep 2020 03:17:37
User entered 'None (0)'	System	13 Sep 2020 03:17:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-12T20:17:22', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'e04ee3c8-57f1-4d06-ba32-648fa0949cc4'	System	13 Sep 2020 03:17:37
User entered 'None (0)'	System	13 Sep 2020 03:17:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-12T20:17:25', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'e04ee3c8-57f1-4d06-ba32-648fa0949cc4'	System	13 Sep 2020 03:17:37
User entered 'None (0)'	System	13 Sep 2020 03:17:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-12T20:17:28', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'e04ee3c8-57f1-4d06-ba32-648fa0949cc4'	System	13 Sep 2020 03:17:37
User entered 'None (0)'	System	13 Sep 2020 03:17:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-12T20:17:30', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'e04ee3c8-57f1-4d06-ba32-648fa0949cc4'	System	13 Sep 2020 03:17:37
User entered 'None (0)'	System	13 Sep 2020 03:17:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-12T20:17:33', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'e04ee3c8-57f1-4d06-ba32-648fa0949cc4'	System	13 Sep 2020 03:17:37
User entered 'No (N)'	System	13 Sep 2020 03:17:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-12T20:17:35', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'e04ee3c8-57f1-4d06-ba32-648fa0949cc4'	System	13 Sep 2020 03:17:37
User entered '12 Sep 2020 20:17'	System	13 Sep 2020 03:17:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 6'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-13T14:07:02', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'bc0a136e-3b12-43d4-a884-5f65ae6543fb' User entered 'None (0)'	System	13 Sep 2020 21:07:27
	System	13 Sep 2020 21:07:27

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-13T14:07:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'bc0a136e-3b12-43d4-a884-5f65ae6543fb' User entered 'None (0)'	System	13 Sep 2020 21:07:27
	System	13 Sep 2020 21:07:27

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-13T14:07:07', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'bc0a136e-3b12-43d4-a884-5f65ae6543fb' User entered 'None (0)'	System	13 Sep 2020 21:07:27
	System	13 Sep 2020 21:07:27

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-13T14:07:13', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'bc0a136e-3b12-43d4-a884-5f65ae6543fb' User entered 'None (0)'	System	13 Sep 2020 21:07:27
	System	13 Sep 2020 21:07:27

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-13T14:07:15', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'bc0a136e-3b12-43d4-a884-5f65ae6543fb' User entered 'None (0)'	System	13 Sep 2020 21:07:27
	System	13 Sep 2020 21:07:27

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-13T14:07:17', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'bc0a136e-3b12-43d4-a884-5f65ae6543fb' User entered 'None (0)'	System	13 Sep 2020 21:07:27
	System	13 Sep 2020 21:07:27

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-13T14:07:21', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'bc0a136e-3b12-43d4-a884-5f65ae6543fb' User entered 'No (N)'	System	13 Sep 2020 21:07:27

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-13T14:07:24', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'bc0a136e-3b12-43d4-a884-5f65ae6543fb' User entered '13 Sep 2020 14:07'	System	13 Sep 2020 21:07:27
	System	13 Sep 2020 21:07:27

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 7'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-15T11:03:37', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5f7a931e-36a6-4b3c-a447-0a45b9039919' User entered 'None (0)'	System	15 Sep 2020 18:03:53
	System	15 Sep 2020 18:03:53

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-15T11:03:39', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5f7a931e-36a6-4b3c-a447-0a45b9039919' User entered 'None (0)'	System	15 Sep 2020 18:03:53
	System	15 Sep 2020 18:03:53

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-15T11:03:41', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5f7a931e-36a6-4b3c-a447-0a45b9039919' User entered 'None (0)'	System	15 Sep 2020 18:03:53
	System	15 Sep 2020 18:03:53

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-15T11:03:43', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5f7a931e-36a6-4b3c-a447-0a45b9039919' User entered 'None (0)'	System	15 Sep 2020 18:03:53
	System	15 Sep 2020 18:03:53

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-15T11:03:45', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5f7a931e-36a6-4b3c-a447-0a45b9039919'	System	15 Sep 2020 18:03:53
User entered 'None (0)'	System	15 Sep 2020 18:03:53

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-15T11:03:47', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5f7a931e-36a6-4b3c-a447-0a45b9039919' User entered 'None (0)'	System	15 Sep 2020 18:03:53
	System	15 Sep 2020 18:03:53

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-15T11:03:50', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5f7a931e-36a6-4b3c-a447-0a45b9039919'	System	15 Sep 2020 18:03:53
User entered 'No (N)'	System	15 Sep 2020 18:03:53

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-15T11:03:52', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5f7a931e-36a6-4b3c-a447-0a45b9039919' User entered '15 Sep 2020 11:03'	System	15 Sep 2020 18:03:53
	System	15 Sep 2020 18:03:53

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 23:20:03

US3772037

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	(b) (4), (b) (6)	15 Sep 2020 23:20:03

US3772037

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	15 Sep 2020 23:20:03

US3772037

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 23:20:03

US3772037

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 23:20:07

US3772037

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 23:20:07

US3772037

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 22:42:41

US3772037

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 22:42:41

US3772037

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Sep 2020 22:42:41

US3772037

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 22:42:41

US3772037

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 22:42:45

US3772037

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 22:42:45

US3772037

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Marisol Corrales (b) (4) (b) (4)	29 Sep 2020 19:20:33

US3772037

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Marisol Corrales (b) (4) (b) (4)	29 Sep 2020 19:20:33

US3772037

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Marisol Corrales (b) (4) (b) (4)	29 Sep 2020 19:20:33

US3772037

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Marisol Corrales (b) (4) (b) (4)	29 Sep 2020 19:20:33

US3772037

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Marisol Corrales (b) (4) (b) (4)	29 Sep 2020 19:20:47

US3772037

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 19:20:47

US3772037

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:12:26

US3772037

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:12:26

US3772037

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:12:26

US3772037

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:06

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	12 Oct 2020 16:12:26

US3772037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:13:19

US3772037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:13:19

US3772037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '08:40'	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:13:19

US3772037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '12 Oct 2020 08:40'	System	12 Oct 2020 16:13:19

US3772037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.3' C	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:13:19

US3772037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:13:19

US3772037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:13:19

US3772037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '64'	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:13:19

US3772037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Oct 2020 16:13:19

US3772037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '17'	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:13:19

US3772037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Oct 2020 16:13:19

US3772037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '121'	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:13:19

US3772037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Oct 2020 16:13:19

US3772037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '65'	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:13:19

US3772037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Oct 2020 16:13:19

US3772037

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:13:26

US3772037

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:13:26

US3772037

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:14:30

US3772037

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:14:30

US3772037

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '09:00'	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:14:30

US3772037

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '12 Oct 2020 09:00'	System	12 Oct 2020 16:14:30

US3772037

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:14:35

US3772037

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 16:14:35

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 64'	System	11 Aug 2020 17:21:08

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-10-11T07:42:38', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'fd33b6f6-4354-483c-81d8-d2228cac43f8'	System	11 Oct 2020 14:42:58
User entered 'No (N)'	System	11 Oct 2020 14:42:58

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

Have you been exposed to someone with 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-10-11T07:42:45', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'fd33b6f6-4354-483c-81d8-d2228cac43f8'	System	11 Oct 2020 14:42:58
User entered 'No (N)'	System	11 Oct 2020 14:42:58

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-10-11T07:42:55', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'fd33b6f6-4354-483c-81d8-d2228cac43f8'	System	11 Oct 2020 14:42:58
User entered '11 Oct 2020 07:42:55'	System	11 Oct 2020 14:42:58

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered '11 Oct 2020 00:01'	System	11 Aug 2020 17:21:08

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered '15 Oct 2020 23:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 71'	System	11 Aug 2020 17:21:08

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-10-18T07:46:10', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9e39e30b-ac00-4ce6-8986-3c52f2c4a78e' User entered 'No (N)'	System	18 Oct 2020 14:46:28
	System	18 Oct 2020 14:46:28

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

Have you been exposed to someone with 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-10-18T07:46:15', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9e39e30b-ac00-4ce6-8986-3c52f2c4a78e'	System	18 Oct 2020 14:46:28
User entered 'No (N)'	System	18 Oct 2020 14:46:28

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-10-18T07:46:24', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9e39e30b-ac00-4ce6-8986-3c52f2c4a78e' User entered '18 Oct 2020 07:46:24'	System	18 Oct 2020 14:46:28
	System	18 Oct 2020 14:46:28

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered '18 Oct 2020 00:01'	System	11 Aug 2020 17:21:08

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered '22 Oct 2020 23:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 78'	System	11 Aug 2020 17:21:08

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-10-25T14:24:33', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '16e434f5-1be8-4b0b-9331-bb2ead9087f1' User entered 'No (N)'	System	25 Oct 2020 21:24:47
	System	25 Oct 2020 21:24:47

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

Have you been exposed to someone with 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-10-25T14:24:38', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '16e434f5-1be8-4b0b-9331-bb2ead9087f1' User entered 'No (N)'	System	25 Oct 2020 21:24:47
	System	25 Oct 2020 21:24:47

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-10-25T14:24:44', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '16e434f5-1be8-4b0b-9331-bb2ead9087f1' User entered '25 Oct 2020 14:24:44'	System	25 Oct 2020 21:24:47
	System	25 Oct 2020 21:24:47

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered '25 Oct 2020 00:01'	System	11 Aug 2020 17:21:08

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered '29 Oct 2020 23:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 92'	System	11 Aug 2020 17:21:08

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:46:46', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029' User entered 'Yes (Y)'	System	08 Nov 2020 10:48:33
	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

Have you been exposed to someone with 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:46:55', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029'	System	08 Nov 2020 10:48:33
User entered 'Yes (Y)'	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:47:03', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029'	System	08 Nov 2020 10:48:33
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:47:09', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029'	System	08 Nov 2020 10:48:33
User entered 'Yes (Y)'	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029' User entered '0'	System	08 Nov 2020 10:48:33
	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029' User entered '0'	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029'	System	08 Nov 2020 10:48:33
User entered '1'	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029' User entered '0'	System	08 Nov 2020 10:48:33
	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029' User entered '0'	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029' User entered '0'	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029' User entered '0'	System	08 Nov 2020 10:48:33
	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029'	System	08 Nov 2020 10:48:33
User entered '0'	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029' User entered '0'	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029' User entered '0'	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029' User entered '0'	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029'	System	08 Nov 2020 10:48:33
User entered '1'	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029' User entered '0'	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029'	System	08 Nov 2020 10:48:33
User entered '0'	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029'	System	08 Nov 2020 10:48:33
User entered '0'	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029' User entered '0'	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029'	System	08 Nov 2020 10:48:33
User entered '0'	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:07', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029'	System	08 Nov 2020 10:48:33
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:13', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029'	System	08 Nov 2020 10:48:33
User entered 'Yes (Y)'	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:16', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029'	System	08 Nov 2020 10:48:33
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:22', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029' User entered '08 Nov 2020 02:48:22'	System	08 Nov 2020 10:48:33
	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered '08 Nov 2020 00:01'	System	11 Aug 2020 17:21:08

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered '12 Nov 2020 23:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 99'	System	11 Aug 2020 17:21:08

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-15T10:28:02', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '3b4becf6-294f-470b-a99e-83a45ee1ae86'	System	15 Nov 2020 18:28:11
User entered 'No (N)'	System	15 Nov 2020 18:28:11

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

Have you been exposed to someone with 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-15T10:28:05', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '3b4becf6-294f-470b-a99e-83a45ee1ae86'	System	15 Nov 2020 18:28:11
User entered 'No (N)'	System	15 Nov 2020 18:28:11

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-15T10:28:08', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '3b4becf6-294f-470b-a99e-83a45ee1ae86'	System	15 Nov 2020 18:28:11
User entered '15 Nov 2020 10:28:08'	System	15 Nov 2020 18:28:11

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered '15 Nov 2020 00:01'	System	11 Aug 2020 17:21:08

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:21:08
User entered '19 Nov 2020 23:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '08 Oct 2020 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '12 Oct 2020 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '15 Oct 2020 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '19 Oct 2020 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '22 Oct 2020 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '26 Oct 2020 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '29 Oct 2020 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '02 Nov 2020 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '05 Nov 2020 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '09 Nov 2020 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '12 Nov 2020 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '16 Nov 2020 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-22T02:58:15', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '16da268c-4a5f-4823-83b8-05ab35b8db3b'	System	22 Nov 2020 10:58:38
User entered 'No (N)'	System	22 Nov 2020 10:58:38

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

Have you been exposed to someone with 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-22T02:58:22', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '16da268c-4a5f-4823-83b8-05ab35b8db3b'	System	22 Nov 2020 10:58:38
User entered 'No (N)'	System	22 Nov 2020 10:58:38

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-22T02:58:33', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '16da268c-4a5f-4823-83b8-05ab35b8db3b' User entered '22 Nov 2020 02:58:33'	System	22 Nov 2020 10:58:38
	System	22 Nov 2020 10:58:38

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 17:31:45

US3772037

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '04 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 17:31:45

US3772037

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Nov 2020 17:31:45

US3772037

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:31:45

US3772037

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 17:31:53

US3772037

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 17:31:53

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:16:06

[Date of Contact](#)

Audit	User	Time (GMT)
User entered '13 Nov 2020'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:44:00

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:16:06

[Time of Contact](#)

Audit	User	Time (GMT)
User entered '14:00'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:44:00

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:16:06

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Nov 2020 14:00'	System	14 Nov 2020 19:44:00

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:16:06

[Type of Contact](#)

Audit	User	Time (GMT)
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:44:00

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:16:06

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:44:00

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:16:06

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:16:06

[Date](#)

Audit	User	Time (GMT)
Query 'Per ETRTR: Per eCRF completion guidelines "Day 1 is the start date of the symptoms begin as reported by subject". COVID-19 AE start date is 07Nov20. Please confirm if symptoms started on 13Nov20, if not, please update as appropriate. ' answered with 'updated ' (Site from CRA).	Marisol Corrales (b) (4)	23 Nov 2020 23:58:28
User entered '07 Nov 2020' reason for change: Data Entry Error	(b) (4)	23 Nov 2020 23:58:20
User opened query 'Per ETRTR: Per eCRF completion guidelines "Day 1 is the start date of the symptoms begin as reported by subject". COVID-19 AE start date is 07Nov20. Please confirm if symptoms started on 13Nov20, if not, please update as appropriate. ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 13:35:11
User entered '13 Nov 2020'	Ruba Zanaid (b) (4)	14 Nov 2020 19:46:16
	(b) (4)	

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:16:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:16:06

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '97'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:16:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:16:06

[Temperature](#)

Audit	User	Time (GMT)
User entered '36.2' C	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:16:06

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:16:06

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:16:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:16:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:16:06

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:16:06

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:16:06

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:16:06

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:16:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:16:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:16:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:16:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:16:06

[Nausea](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:16:06

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:16:06

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:16:06

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:16:06

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:16:06

[Date](#)

Audit	User	Time (GMT)
User entered '14 Nov 2020'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:16:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:16:06

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '94'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:16:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:16:06

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.1' F	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:16:06

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:16:06

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:16:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:16:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:16:06

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:16:06

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:16:06

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:16:06

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:16:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:16:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:16:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:16:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:16:06

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:16:06

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:16:06

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:16:06

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:16:06

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)'	(b) (4), (b) (6)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:16:06

[Date](#)

Audit	User	Time (GMT)
User entered '16 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:16:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:16:06

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '95'	(b) (4), (b) (6)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:16:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:16:06

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.6' F	(b) (4), (b) (6)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:16:06

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:16:06

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:16:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:16:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:16:06

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:16:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:16:06

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:16:06

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:16:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:16:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:16:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:16:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:16:06

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:16:06

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:16:06

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:16:06

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:16:06

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	(b) (4), (b) (6)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:16:06

[Date](#)

Audit	User	Time (GMT)
User entered '15 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:16:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:16:06

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '94'	(b) (4), (b) (6)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:16:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:16:06

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.1' F	(b) (4), (b) (6)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:16:06

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:16:06

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:16:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:16:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:16:06

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:16:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:16:06

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:16:06

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:16:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:16:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:16:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:16:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:16:06

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:16:06

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:16:06

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:16:06

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:16:06

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:16:06

[Date](#)

Audit	User	Time (GMT)
User entered '17 Nov 2020'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:16:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:16:06

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '94'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:16:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:16:06

[Temperature](#)

Audit	User	Time (GMT)
User entered '36.5' C	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:16:06

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:16:06

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:16:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:16:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:16:06

Fatigue

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:16:06

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:16:06

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:16:06

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:16:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:16:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:16:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:16:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:16:06

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:16:06

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:16:06

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:16:06

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:16:06

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:16:06

[Date](#)

Audit	User	Time (GMT)
User entered '18 Nov 2020'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:16:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:16:06

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '91'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:16:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:16:06

[Temperature](#)

Audit	User	Time (GMT)
User entered '36.7' C	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:16:06

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:16:06

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:16:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:16:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:16:06

Fatigue

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:16:06

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:16:06

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:16:06

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:16:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:16:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:16:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:16:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:16:06

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:16:06

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:16:06

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:16:06

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:16:06

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:16:06

[Date](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:16:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:16:06

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '93'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:16:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:16:06

[Temperature](#)

Audit	User	Time (GMT)
User entered '36.7' C	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:16:06

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:16:06

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:16:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:16:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:16:06

Fatigue

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:16:06

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:16:06

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:16:06

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:16:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:16:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:16:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:16:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:16:06

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:16:06

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:16:06

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:16:06

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:16:06

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:16:06

[Date](#)

Audit	User	Time (GMT)
User entered '20 Nov 2020'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:16:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:16:06

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '94'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:16:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:16:06

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.1' F	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:16:06

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:16:06

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:16:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:16:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:16:06

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:16:06

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:16:06

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:16:06

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:16:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:16:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:16:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:16:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:16:06

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:16:06

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:16:06

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:16:06

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:16:06

[Date of Visit](#)

Audit	User	Time (GMT)
User entered '13 Nov 2020'	(b) (4), (b) (6)	21 Nov 2020 00:27:51

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:16:06

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Nov 2020 00:27:51

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:16:06

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Nov 2020 00:27:51

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:16:06

[Date of Test](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	(b) (4), (b) (6)	21 Nov 2020 00:27:51

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:16:06

[Type of Test Performed](#)

Audit	User	Time (GMT)
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	21 Nov 2020 00:27:51

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:16:06

[Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Nov 2020 00:27:51

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:16:06

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Nov 2020 00:27:51

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:16:06

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Nov 2020 00:27:51

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:16:06

[CLIA Certified?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Nov 2020 00:27:51

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:16:06

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Nov 2020 00:27:51

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:16:06

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:43:14

US3772037

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 13NOV2020 is reported under Illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 11:36:25
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 13NOV2020 is reported under Illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'There is no ecrf to complete for swab on Illness Day 1. Blood sampling is documented' (Site from DM).	Emily Crews (b) (4) (b) (4)	18 Nov 2020 23:39:30
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 13NOV2020 is reported under Illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:38:35
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	13 Nov 2020 22:53:48

US3772037

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '13 Nov 2020'	Emily Crews (b) (4) (b) (4)	13 Nov 2020 22:53:48

US3772037

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Emily Crews (b) (4) (b) (4)	13 Nov 2020 22:53:48

US3772037

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:06

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	13 Nov 2020 22:53:48

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	13 Nov 2020 22:56:55

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '13 Nov 2020'	Emily Crews (b) (4) (b) (4)	13 Nov 2020 22:56:55

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '14:15'	Emily Crews (b) (4) (b) (4)	13 Nov 2020 22:56:55

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '13 Nov 2020 14:15'	System	13 Nov 2020 22:56:55

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Emily Crews (b) (4)	13 Nov 2020 22:56:55
DataPoint set to visible.	(b) (4) System	13 Nov 2020 22:53:48

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Emily Crews (b) (4)	13 Nov 2020 22:56:55
DataPoint set to visible.	(b) (4) System	13 Nov 2020 22:53:48

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.2' C	Emily Crews (b) (4) (b) (4)	13 Nov 2020 22:56:55

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Emily Crews (b) (4) (b) (4)	13 Nov 2020 22:56:55

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	13 Nov 2020 22:56:55

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '75'	Emily Crews (b) (4) (b) (4)	13 Nov 2020 22:56:55

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Nov 2020 22:56:55

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '15'	Emily Crews (b) (4) (b) (4)	13 Nov 2020 22:56:55

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Nov 2020 22:56:55

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '132'	Emily Crews (b) (4) (b) (4)	13 Nov 2020 22:56:55

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Nov 2020 22:56:55

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '70'	Emily Crews (b) (4) (b) (4)	13 Nov 2020 22:56:55

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Nov 2020 22:56:55

US3772037

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	13 Nov 2020 22:57:04

US3772037

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '13 Nov 2020'	Emily Crews (b) (4) (b) (4)	13 Nov 2020 22:57:04

US3772037

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 11:16:06

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	13 Nov 2020 22:57:13

US3772037

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 11:16:06

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '13 Nov 2020'	Emily Crews (b) (4) (b) (4)	13 Nov 2020 22:57:13

US3772037

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:16:06

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:04:26

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:10
User entered 'USA-US107-2020-mRNA-1273-P301000002'	System	10 Nov 2020 15:42:05
User entered 'New'	(b) (4), (b) (6)	10 Nov 2020 15:42:05

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Acute respiratory failure, LLT: Acute respiratory failure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:19:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:19:10
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Respiratory failure, LLT: Hypoxic respiratory failure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:14:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:14:57
Data point term sent to Coder	System	24 Nov 2020 18:01:56
Coding entries removed.	Emily Crews (b) (4) (b) (4)	24 Nov 2020 18:01:14
User entered 'Acute Hypoxic Respiratory Failure due to COVID-19 Infection' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	24 Nov 2020 18:01:14
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 19:11:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 19:11:35
Data point term sent to Coder	System	09 Nov 2020 19:11:02
User entered 'COVID-19 Infection'	Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: The start date of the event is 07 Nov 2020. Did the subject report any symptoms on that day? If yes, please add 07 Nov 2020 to the COVID-19 assessment symptom log in EDC.' answered with 'Updated SAE term' (Site from Safety).	Emily Crews (b) (4) (b) (4)	24 Nov 2020 18:01:35
User opened query 'PV Query: The start date of the event is 07 Nov 2020. Did the subject report any symptoms on that day? If yes, please add 07 Nov 2020 to the COVID-19 assessment symptom log in EDC.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	23 Nov 2020 18:56:42
User entered '07 Nov 2020'	Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	24 Nov 2020 18:10:14
User entered 'No (N)' reason for change: Data Entry Error	Emily Crews (b) (4)	24 Nov 2020 18:10:14
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	24 Nov 2020 18:01:14
User entered 'Yes (Y)'	Emily Crews (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (when symptoms have resolved). ' answered with 'Updated' (Site from Safety).	Emily Crews (b) (4) (b) (4)	24 Nov 2020 18:01:41
User entered '12 Nov 2020' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	24 Nov 2020 18:01:14
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved). ' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Nov 2020 18:56:00
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 16:09:03
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'event is ongoing' (Site from Safety).	Emily Crews (b) (4) (b) (4)	18 Nov 2020 23:08:07
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	16 Nov 2020 21:09:31
User entered empty.	Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

[Severity](#)

Audit	User	Time (GMT)
Query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' answered with 'UPdated' (Site from Safety).	Emily Crews (b) (4) (b) (4)	24 Nov 2020 18:01:45
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	24 Nov 2020 18:01:14
User opened query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	23 Nov 2020 18:56:52
User entered 'Grade 3/Severe (Grade 3/Severe)'	Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Query 'per CDM RQ: please respond to this query when data is entered' answered with 'Updated' (Site from DM).	Emily Crews (b) (4) (b) (4)	24 Nov 2020 18:01:57
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6) (b) (4)	19 Nov 2020 17:28:34
User opened query 'per CDM RQ: please respond to this query when data is entered' (Site from DM).	(b) (4), (b) (6) (b) (4)	19 Nov 2020 17:28:33
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Subject is still in the hospital there is not a discharge date available' (Site from System).	Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:11:15
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	09 Nov 2020 19:10:35
User entered '1'	Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '08 Nov 2020'	Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '12 Nov 2020' reason for change: Data Entry Error	Emily Crews (b) (4)	16 Nov 2020 19:04:08
User entered empty.	Emily Crews (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

[None](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

[Outcome](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Updated' (Site from Safety).	Emily Crews (b) (4) (b) (4)	24 Nov 2020 18:02:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	24 Nov 2020 18:01:14
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	23 Nov 2020 18:56:28
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	19 Nov 2020 16:09:30
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Ongoing' (Site from Safety).	Emily Crews (b) (4) (b) (4)	18 Nov 2020 23:12:24
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	16 Nov 2020 21:10:25
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Conmeds have been updated' (Site from Safety).	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:20:36
Query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' answered with 'Site has not received the requested positive test results. The GCL test came back negative. Until we receive the positive test results it cannot be entered into EDC therefore the severity assessment will not be populated' (Site from Safety).	Emily Crews (b) (4) (b) (4)	24 Nov 2020 18:05:45
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Nov 2020 18:56:13
User opened query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Nov 2020 18:55:45
User closed query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 16:08:49
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 16:08:39

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Awaiting receipt of medical records' (Site from Safety).	Emily Crews (b) (4)	18 Nov 2020 23:17:10
Query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' answered with 'Awaiting receipt of medical records for covid testing' (Site from Safety).	Emily Crews (b) (4)	18 Nov 2020 23:16:59
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 21:10:06
User opened query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 21:08:06
User entered 'Subject was contacted regarding safety report of Covid exposure and symptoms. The subject reported being tested for Covid on the same day they were Dx with Sinusitis (05 Nov 2020) and receiving a positive result on 07 Nov 2020. The subject was advised to go to the hospital if their oxygen saturation was below 90. The Subject reported having an O2 saturation of 88 on 8th of November. Self referred to ER. The subject was admitted as an Inpatient on 08 Nov 2020. Medical records have been requested for COVID test RESULTS and hospital stay.'	Emily Crews (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '0'	System	09 Nov 2020 19:10:35

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:16:06

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:24:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:06

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:09:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:09:54
Data point term sent to Coder	System	11 Aug 2020 17:26:10
User entered 'Potassium chloride'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:06

[Indication](#)

Audit	User	Time (GMT)
User entered 'Kypokalemia'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:06

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:06

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'meq'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:06

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
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 17:56:55
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 17:25:51
User entered 'un UNK 2010'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:06

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:28:11
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 17:28:11
Data point term sent to Coder	System	11 Aug 2020 17:27:13
User entered 'Rosuvastatin'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:06

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hyperlipidemia'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:06

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:06

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:06

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
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 17:57:09
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 17:26:27
User entered 'un UNK 2010'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:06

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:28:11
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 17:28:11
Data point term sent to Coder	System	11 Aug 2020 17:27:14
User entered 'Amlodipine'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:06

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hypertension'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:06

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '5'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:06

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:06

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
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 17:57:18
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 17:27:05
User entered 'un UNK 2010'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:06

[Name of Medication](#)

Audit	User	Time (GMT)
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 17:29:13
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 17:29:13
Data point term sent to Coder	System	11 Aug 2020 17:28:14
User entered 'Levothyroxine'	Emily Crews (b) (4)	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:06

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hypothyroidism'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:06

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '25'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:06

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'ug (ug)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:06

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
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 17:57:27
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 17:27:47
User entered 'un UNK 2010'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:06

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 00:12:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 00:12:51
Data point term sent to Coder Coding entries removed.	System Emily Crews (b) (4) (b) (4)	06 Oct 2020 23:02:10 06 Oct 2020 23:01:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:30:11
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 17:30:11
Data point term sent to Coder User entered 'Gabapentin'	System Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:16 11 Aug 2020 17:29:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:06

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the location/type of NEUROPATHY. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:06:41
Query 'Per DM CLR: Please update the indication to reflect the location/type of NEUROPATHY. Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'Updated' (Site from DM).	Emily Crews (b) (4)	06 Oct 2020 23:02:02
User entered 'NEUROPATHY (Right Ankle)' reason for change: Data Entry Error	Emily Crews (b) (4)	06 Oct 2020 23:01:55
User opened query 'Per DM CLR: Please update the indication to reflect the location/type of NEUROPATHY. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 06:02:47
User entered 'Neuropathy'	Emily Crews (b) (4)	11 Aug 2020 17:29:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:06

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:06

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)' reason for change:	Emily Crews (b) (4)	11 Aug 2020 17:31:12
Data Entry Error	(b) (4)	
User entered 'once daily (QD)'	Emily Crews (b) (4)	11 Aug 2020 17:29:05
	(b) (4)	

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:06

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
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 17:57:34
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 17:29:05
User entered 'un UNK 2014'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	11 Aug 2020 17:31:12
User entered '1'	System	11 Aug 2020 17:29:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 17:29:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 17:29:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:16:06

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:31:12
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 17:31:12
Data point term sent to Coder	System	11 Aug 2020 17:30:17
User entered 'Hydrochlorothiazide'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:16:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:16:06

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hypertension'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:16:06

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '25'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:16:06

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:16:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:16:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:16:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:16:06

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:16:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
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 17:57:42
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 17:29:43
User entered 'un UNK 2010'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:16:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:16:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:16:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:16:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:16:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:16:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:16:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:16:06

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:32:15
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 17:32:15
Data point term sent to Coder	System	11 Aug 2020 17:31:18
User entered 'Symbicort'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:16:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:16:06

[Indication](#)

Audit	User	Time (GMT)
User entered 'Asthma'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:16:06

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '160/4.5'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:16:06

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:06:48
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'Updated' (Site from DM).	Emily Crews (b) (4) (b) (4)	06 Oct 2020 23:02:31
User entered 'ug (ug)' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	06 Oct 2020 23:02:25
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 06:03:06
User entered 'mg (mg)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:16:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:16:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:16:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:16:06

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:16:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
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 17:57:50
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 17:30:48
User entered 'un UNK 2015'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:16:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:16:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:16:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:16:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:16:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:16:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:16:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:06

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 15:46:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 15:46:23
Data point term sent to Coder User entered 'Tylenol'	System	14 Aug 2020 15:45:02
	Emily Crews (b) (4)	14 Aug 2020 15:44:13
DataPoint activated with code reason code Data required.	Emily Crews (b) (4)	14 Aug 2020 15:43:32
DataPoint inactivated with code reason code Data not required.	Emily Crews (b) (4)	11 Aug 2020 17:31:29

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4)	14 Aug 2020 15:44:13
DataPoint activated with code reason code Data required.	Emily Crews (b) (4)	14 Aug 2020 15:43:32
DataPoint inactivated with code reason code Data not required.	Emily Crews (b) (4)	11 Aug 2020 17:31:29

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:06

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:06:52
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria.' answered with 'updated' (Site from DM).	Emily Crews (b) (4) (b) (4)	06 Oct 2020 23:03:08
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 06:03:27
User entered 'Pain at injection site'	Emily Crews (b) (4) (b) (4)	14 Aug 2020 15:44:13

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:06

[Indication](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Emily Crews (b) (4)	14 Aug 2020 15:43:32
DataPoint inactivated with code reason code Data not required.	Emily Crews (b) (4)	11 Aug 2020 17:31:29

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:06

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '500'	Emily Crews (b) (4)	14 Aug 2020 15:44:13
DataPoint activated with code reason code Data required.	Emily Crews (b) (4)	14 Aug 2020 15:43:32
DataPoint inactivated with code reason code Data not required.	Emily Crews (b) (4)	11 Aug 2020 17:31:29

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:06

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Emily Crews (b) (4)	14 Aug 2020 15:44:13
DataPoint activated with code reason code Data required.	Emily Crews (b) (4)	14 Aug 2020 15:43:32
DataPoint inactivated with code reason code Data not required.	Emily Crews (b) (4)	11 Aug 2020 17:31:29

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4)	14 Aug 2020 15:44:13
DataPoint activated with code reason code Data required.	Emily Crews (b) (4)	14 Aug 2020 15:43:32
DataPoint inactivated with code reason code Data not required.	Emily Crews (b) (4)	11 Aug 2020 17:31:29

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Emily Crews (b) (4)	14 Aug 2020 15:44:13
DataPoint activated with code reason code Data required.	Emily Crews (b) (4)	14 Aug 2020 15:43:32
DataPoint inactivated with code reason code Data not required.	Emily Crews (b) (4)	11 Aug 2020 17:31:29

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4)	14 Aug 2020 15:44:13
DataPoint activated with code reason code Data required.	Emily Crews (b) (4)	14 Aug 2020 15:43:32
DataPoint inactivated with code reason code Data not required.	Emily Crews (b) (4)	11 Aug 2020 17:31:29

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:06

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Emily Crews (b) (4)	14 Aug 2020 15:44:13
DataPoint activated with code reason code Data required.	Emily Crews (b) (4)	14 Aug 2020 15:43:32
DataPoint inactivated with code reason code Data not required.	Emily Crews (b) (4)	11 Aug 2020 17:31:29

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4)	14 Aug 2020 15:44:13
DataPoint activated with code reason code Data required.	Emily Crews (b) (4)	14 Aug 2020 15:43:32
DataPoint inactivated with code reason code Data not required.	Emily Crews (b) (4)	11 Aug 2020 17:31:29

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Emily Crews (b) (4)	14 Aug 2020 15:44:13
DataPoint activated with code reason code Data required.	Emily Crews (b) (4)	14 Aug 2020 15:43:32
DataPoint inactivated with code reason code Data not required.	Emily Crews (b) (4)	11 Aug 2020 17:31:29

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4)	14 Aug 2020 15:44:13
DataPoint activated with code reason code Data required.	Emily Crews (b) (4)	14 Aug 2020 15:43:32
DataPoint inactivated with code reason code Data not required.	Emily Crews (b) (4)	11 Aug 2020 17:31:29

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4)	14 Aug 2020 15:44:13
DataPoint activated with code reason code Data required.	Emily Crews (b) (4)	14 Aug 2020 15:43:32
DataPoint inactivated with code reason code Data not required.	Emily Crews (b) (4)	11 Aug 2020 17:31:29

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Emily Crews (b) (4)	14 Aug 2020 15:44:13
DataPoint activated with code reason code Data required.	Emily Crews (b) (4)	14 Aug 2020 15:43:32
DataPoint inactivated with code reason code Data not required.	Emily Crews (b) (4)	11 Aug 2020 17:31:29

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Emily Crews (b) (4)	06 Oct 2020 23:02:39
User entered 'Yes (Y)'	Emily Crews (b) (4)	14 Aug 2020 15:44:13
DataPoint activated with code reason code Data required.	Emily Crews (b) (4)	14 Aug 2020 15:43:32
DataPoint inactivated with code reason code Data not required.	Emily Crews (b) (4)	11 Aug 2020 17:31:29

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 15:44:13
DataPoint activated with code reason code Data required.	Emily Crews (b) (4)	14 Aug 2020 15:43:32
DataPoint inactivated with code reason code Data not required.	Emily Crews (b) (4)	11 Aug 2020 17:31:29

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 15:44:13
DataPoint activated with code reason code Data required.	Emily Crews (b) (4)	14 Aug 2020 15:43:32
DataPoint inactivated with code reason code Data not required.	Emily Crews (b) (4)	11 Aug 2020 17:31:29

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 15:44:13
DataPoint activated with code reason code Data required.	Emily Crews (b) (4)	14 Aug 2020 15:43:32
DataPoint inactivated with code reason code Data not required.	Emily Crews (b) (4)	11 Aug 2020 17:31:29

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:16:06

[Name of Medication](#)

Audit	User	Time (GMT)
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) (b) (4)	23 Nov 2020 22:20:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 22:20:59
Data point term sent to Coder	System	23 Nov 2020 22:19:33
User entered 'Influenza Vaccination'	(b) (4), (b) (6) (b) (4)	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:16:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:16:06

[Indication](#)

Audit	User	Time (GMT)
User entered 'Influenza Prophylaxis'	(b) (4), (b) (6)	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:16:06

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '0.5'	(b) (4), (b) (6)	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:16:06

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mL (mL)'	(b) (4), (b) (6)	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:16:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:16:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	(b) (4), (b) (6)	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:16:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:16:06

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:16:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '27 Oct 2020'	(b) (4), (b) (6)	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:16:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:16:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:16:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '27 Oct 2020'	(b) (4), (b) (6)	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:16:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:16:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:16:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:16:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:16:06

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: OTHER RESPIRATORY SYSTEM PRODUCTS, ATC: OTHER RESPIRATORY SYSTEM PRODUCTS, ATC: OTHER RESPIRATORY SYSTEM PRODUCTS, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 20:41:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 20:41:39
Data point term sent to Coder	System	24 Nov 2020 19:06:35
User entered 'Dexamethasone (Decadron)'	Emily Crews (b) (4)	24 Nov 2020 19:05:44

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:16:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:05:44

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:16:06

[Indication](#)

Audit	User	Time (GMT)
User entered 'COVID-19'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:05:44

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:16:06

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '6/1.5'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:05:44

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:16:06

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:05:44

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:16:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'mg/mL'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:05:44

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:16:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:05:44

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:16:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:05:44

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:16:06

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous (INTRAVENOUS)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:05:44

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:16:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:05:44

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '07 Nov 2020'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:05:44

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:16:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:05:44

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:16:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:05:44

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:16:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '12 Nov 2020'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:05:44

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:16:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:05:44

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:16:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 19:05:44

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:16:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 19:05:44

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:16:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Nov 2020 19:05:44

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:16:06

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFDINIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 22:35:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 22:35:06
Data point term sent to Coder	System	23 Nov 2020 22:33:53
User entered 'Cefdinir'	(b) (4), (b) (6)	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:16:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:16:06

[Indication](#)

Audit	User	Time (GMT)
User entered 'Sinusitis'	(b) (4), (b) (6)	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:16:06

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '300'	(b) (4), (b) (6)	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:16:06

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:16:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:16:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	(b) (4), (b) (6)	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:16:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:16:06

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:16:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '05 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:16:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:16:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:16:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '07 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:16:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:16:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:16:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:16:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:06

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 09:19:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 09:19:14
Data point term sent to Coder	System	23 Nov 2020 22:41:07
User entered 'Advil'	(b) (4), (b) (6)	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:06

[Indication](#)

Audit	User	Time (GMT)
User entered 'Sinusitis'	(b) (4), (b) (6)	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:06

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '200'	(b) (4), (b) (6)	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:06

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	(b) (4), (b) (6)	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:06

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '05 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '05 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:16:06

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 19:20:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 19:20:00
Data point term sent to Coder	System	24 Nov 2020 19:18:52
User entered 'Dexamethasone'	Emily Crews (b) (4)	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:16:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:16:06

[Indication](#)

Audit	User	Time (GMT)
User entered 'COVID-19'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:16:06

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '6'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:16:06

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:16:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:16:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:16:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:16:06

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:16:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '13 Nov 2020'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:16:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:16:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:16:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Nov 2020'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:16:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:16:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:16:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:16:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:16:06

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 02:32:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 02:32:22
Data point term sent to Coder	System	24 Nov 2020 19:19:53
User entered 'Supplemental Oxygen'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:16:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:16:06

[Indication](#)

Audit	User	Time (GMT)
User entered 'COVID-19'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:16:06

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:16:06

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:16:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'Liter'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:16:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'other (OTHER)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:16:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered 'Continuous'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:16:06

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Nasal (NASAL)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:16:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '08 Nov 2020'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:16:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:16:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:16:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Nov 2020'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:16:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:16:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:16:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:16:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:16:06

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE, PRODUCTSYNONYM: DUONEB - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:19:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:19:09
Data point term sent to Coder	System	24 Nov 2020 19:20:55
User entered 'DuoNeb treatment (Ipratropium Bromide/ Albuterol Sulfate)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:20:16

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:16:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:20:16

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:16:06

[Indication](#)

Audit	User	Time (GMT)
User entered 'COVID-19'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:20:16

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:16:06

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '0.5/3/3'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:20:16

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:16:06

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:20:16

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:16:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'mg/mg/mL'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:20:16

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:16:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:20:16

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:16:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:20:16

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:16:06

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:20:16

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:16:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:20:16

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:16:06

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

Audit	User	Time (GMT)
User entered '07 Nov 2020'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:20:16

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:16:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:20:16

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:16:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:20:16

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:16:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '07 Nov 2020'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:20:16

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:16:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:20:16

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:16:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 19:20:16

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:16:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 19:20:16

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:16:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 19:20:16

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'USA-US107-2020-MRNA-1273-P301000002'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Yes (Y)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Yes (Y)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Jamshid'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Saleh'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered '3652 Eureka Way'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Site Address:](#) City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Redding'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:19
Un-reviewed for Safety.	System	17 Nov 2020 19:07:25
User entered empty.	System	17 Nov 2020 19:07:25
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:07:14
User entered 'California'	Emily Crews (b) (4)	16 Nov 2020 19:03:23
	(b) (4)	

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered '96001'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:07:14
User entered 'US'	System	10 Nov 2020 15:42:46

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Nov 2020 16:10:42
User entered '2'	System	17 Nov 2020 19:07:25
User entered '1'	System	10 Nov 2020 15:42:46

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'USA-US107-2020-MRNA-1273-P301000002'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Yes (Y)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Yes (Y)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Jamshid'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Saleh'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered '3652 Eureka Way'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Site Address:](#) City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Redding'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:19
Un-reviewed for Safety.	System	17 Nov 2020 19:07:25
User entered empty.	System	17 Nov 2020 19:07:25
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:07:14
User entered 'California'	Emily Crews (b) (4)	16 Nov 2020 19:03:23
	(b) (4)	

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered '96001'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:07:14
User entered 'US'	System	10 Nov 2020 15:42:46

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Nov 2020 16:10:42
User entered '2'	System	17 Nov 2020 19:07:25
User entered '1'	System	10 Nov 2020 15:42:46

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:16:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '10/Nov/2020 10:42'	System	10 Nov 2020 15:42:46

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:16:06

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)	17 Nov 2020 19:07:14
User entered '1'	(b) (4), (b) (6)	10 Nov 2020 15:42:46

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'USA-US107-2020-MRNA-1273-P301000002'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Yes (Y)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Yes (Y)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Jamshid'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Saleh'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered '3652 Eureka Way'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Site Address:](#) City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Redding'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:19
Un-reviewed for Safety.	System	17 Nov 2020 19:07:25
User entered empty.	System	17 Nov 2020 19:07:25
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:07:14
User entered 'California'	Emily Crews (b) (4)	16 Nov 2020 19:03:23
	(b) (4)	

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered '96001'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:07:14
User entered 'US'	System	10 Nov 2020 15:42:46

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Nov 2020 16:10:42
User entered '2'	System	17 Nov 2020 19:07:25
User entered '1'	System	10 Nov 2020 15:42:46

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:16:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '17/Nov/2020 19:07'	System	17 Nov 2020 19:07:25

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:16:06

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)	19 Nov 2020 16:10:19
User entered '1'	(b) (4), (b) (6)	17 Nov 2020 19:07:25

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'USA-US107-2020-MRNA-1273-P301000002'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Yes (Y)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Yes (Y)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Jamshid'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Saleh'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered '3652 Eureka Way'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Site Address:](#) City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Redding'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:19
Un-reviewed for Safety.	System	17 Nov 2020 19:07:25
User entered empty.	System	17 Nov 2020 19:07:25
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:07:14
User entered 'California'	Emily Crews (b) (4)	16 Nov 2020 19:03:23
	(b) (4)	

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered '96001'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:07:14
User entered 'US'	System	10 Nov 2020 15:42:46

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Nov 2020 16:10:42
User entered '2'	System	17 Nov 2020 19:07:25
User entered '1'	System	10 Nov 2020 15:42:46

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:16:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '19/Nov/2020 11:10'	System	19 Nov 2020 16:10:42

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:16:06

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 entered '1'	(b) (4), (b) (6)	19 Nov 2020 16:10:42