

US3802046 (Prod: UPMC University Center)

Generated By: (b) (6)

Generated On: 26 Nov 2020 11:20:44

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US3802046

Form: Participant Creation

Data signed: (b) (4) 09 Sep 2020 18:08:39

Generated On: 26 Nov 2020 11:20:44

[Participant ID](#)

US3802046

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

US3802046

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 09 Sep 2020 18:08:39

Generated On: 26 Nov 2020 11:20:44

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	26 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

Data signed: (b) (4) 09 Sep 2020 18:08:39

Generated On: 26 Nov 2020 11:20:44

Date of Birth (MMM yyyy)	(b) (6) 1950
Age	70
Age Units	YEARS
Age (Derived)	70
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

US3802046

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 09 Sep 2020 18:08:39

Generated On: 26 Nov 2020 11:20:44

Date of Informed Consent (<i>dd MMM yyyy</i>)	26 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

Data signed: (b) (4) 09 Sep 2020 18:08:39

Generated On: 26 Nov 2020 11:20:44

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 09 Sep 2020 18:08:39

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:20:44

Condition	ALLERGIES SULFA
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:20:44

Condition	ALLERGIES CEPHALOSPORIN
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:20:44

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:20:44

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

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:20:44

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:20:44

Condition	ANXIETY
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:20:44

Condition	ACID INDIGESTION
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3802046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	26 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	15:19 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 15:19
Height (<i>xxx.x</i>)	157 cm
Weight (<i>xxx.x</i>)	133 lb
BMI (<i>xxx.x</i>)	24.52617 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	97.5 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	INFRARED
Pulse (<i>xxx</i>)	72 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 09 Sep 2020 18:08:39

Generated On: 26 Nov 2020 11:20:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 09 Sep 2020 18:08:38

Generated On: 26 Nov 2020 11:20:44

Date of assessment (dd MMM yyyy) 26 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____
If Surgically sterile, date of surgery (dd MMM yyyy) _____
Date of surgery unknown False
If Post-menopausal, date of last menstruation (dd MMM yyyy) _____
Date of last menstruation unknown True

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 09 Sep 2020 18:08:39

Generated On: 26 Nov 2020 11:20:44

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 09 Sep 2020 18:08:39

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 09 Sep 2020 18:08:39

Generated On: 26 Nov 2020 11:20:44

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	26 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 11:20:44

What was the date of randomization? (dd MMM yyyy) 26 AUG 2020

What was the participant's randomization number? 188343

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 09 Sep 2020 18:08:39

Generated On: 26 Nov 2020 11:20:44

Height	157 cm
Weight	133 lb

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Sep 2020 18:08:39

Generated On: 26 Nov 2020 11:20:44

Height	157 cm
Weight	133 lb
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	15:19 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 15:19
Temperature (xxx.x)	97.5 F
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	INFRARED
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Sep 2020 18:08:39

Generated On: 26 Nov 2020 11:20:44

Height	157 cm
Weight	133 lb
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	16:26 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 16:26
Temperature (xxx.x)	97.7 F
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	INFRARED
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 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: Physical Examination

Data signed: (b) (4) 09 Sep 2020 18:08:39

Generated On: 26 Nov 2020 11:20:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 09 Sep 2020 18:08:39

Generated On: 26 Nov 2020 11:20:44

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) 26 AUG 2020

What was the treatment time? (00:00-23:59) 15:54 (24 HR)

Treatment Date and Time (derived) 26 AUG 2020 15:54

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Sep 2020 18:08:38

Generated On: 26 Nov 2020 11:20:44

Was the sample collected?	Yes ☒
	No ☐

Collection date (dd MMM yyyy)	26 AUG 2020
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Collection time (00:00-23:59)	15:31 (24 HR)
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Collection date and time (derived)	26 AUG 2020 15:31
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US3802046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 09 Sep 2020 18:08:39

Generated On: 26 Nov 2020 11:20:44

Collection date (dd MMM yyyy)			26 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:27	26 AUG 2020 15:27
Nasopharyngeal Swab 2	No		

US3802046

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 09 Sep 2020 18:08:38

Generated On: 26 Nov 2020 11:20:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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

26 AUG 2020 16:37

PC Open Date & Time

26 AUG 2020 16:14

PC Close Date & Time

26 AUG 2020 18:44

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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

97.0 °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

26 AUG 2020 20:29

PC Open Date & Time

26 AUG 2020 19:39

PC Close Date & Time

27 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 19:07

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

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

97.7 °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

28 AUG 2020 19:46

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

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

97.2 °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

29 AUG 2020 22:07

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

30 AUG 2020 20:49

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

31 AUG 2020 21:22

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

01 SEP 2020 20:12

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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

26 AUG 2020 16:38

PC Open Date & Time

26 AUG 2020 16:14

PC Close Date & Time

26 AUG 2020 18:44

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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

26 AUG 2020 20:30

PC Open Date & Time

26 AUG 2020 19:39

PC Close Date & Time

27 AUG 2020 11:59

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 19:08

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

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

28 AUG 2020 19:47

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

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

29 AUG 2020 22:07

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

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

30 AUG 2020 20:49

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

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

31 AUG 2020 21:22

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

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

01 SEP 2020 20:13

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 16:38
PC Open Date & Time	26 AUG 2020 16:14
PC Close Date & Time	26 AUG 2020 18:44

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 20:31
PC Open Date & Time	26 AUG 2020 19:39
PC Close Date & Time	27 AUG 2020 11:59

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

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 ☒

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

Yes ☐	
PC Time stamp	27 AUG 2020 19:07
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

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 ☒

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

Yes ☐	
PC Time stamp	28 AUG 2020 19:48
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

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 ☒

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

Yes ☐	
PC Time stamp	29 AUG 2020 22:08
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

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 ☒

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

Yes ☐	
PC Time stamp	30 AUG 2020 20:49
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

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 ☒

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

Yes ☐	
PC Time stamp	31 AUG 2020 21:23
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

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 ☒

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

Yes ☐	
PC Time stamp	01 SEP 2020 20:13
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3802046

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 09 Sep 2020 18:08:39

Generated On: 26 Nov 2020 11:20:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3802046

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 09 Sep 2020 18:08:38

Generated On: 26 Nov 2020 11:20:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802046

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 09 Sep 2020 18:08:39

Generated On: 26 Nov 2020 11:20:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3802046

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 09 Sep 2020 18:08:38

Generated On: 26 Nov 2020 11:20:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802046

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 18 Sep 2020 13:57:43

Generated On: 26 Nov 2020 11:20:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3802046

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 18 Sep 2020 13:57:43

Generated On: 26 Nov 2020 11:20:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802046

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 08 Oct 2020 19:06:29

Generated On: 26 Nov 2020 11:20:44

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	23 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3802046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Oct 2020 19:06:29

Generated On: 26 Nov 2020 11:20:44

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	23 SEP 2020
Time of assessment (00:00-23:59)	9:10 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 9:10
Temperature (xxx.x)	97.2 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	INFRARED
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3802046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Oct 2020 19:06:29

Generated On: 26 Nov 2020 11:20:44

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	23 SEP 2020
Time of assessment (00:00-23:59)	9:51 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 9:51
Temperature (xxx.x)	96.7 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	INFRARED
Pulse (xxx)	61 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)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3802046

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Oct 2020 19:06:29

Generated On: 26 Nov 2020 11:20:44

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.

US3802046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 08 Oct 2020 19:06:29

Generated On: 26 Nov 2020 11:20:44

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) 23 SEP 2020

What was the treatment time? (00:00-23:59) 09:18 (24 HR)

Treatment Date and Time (derived) 23 SEP 2020 09:18

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

US3802046

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Oct 2020 19:06:29

Generated On: 26 Nov 2020 11:20:44

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 SEP 2020

Collection time (00:00-23:59)

09:10 (24 HR)

Collection date and time (derived)

23 SEP 2020 09:10

US3802046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 08 Oct 2020 19:06:29

Generated On: 26 Nov 2020 11:20:44

Collection date (dd MMM yyyy)			23 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:05	23 SEP 2020 09:05
Nasopharyngeal Swab 2	No		

US3802046

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 08 Oct 2020 19:06:29

Generated On: 26 Nov 2020 11:20:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °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

23 SEP 2020 10:06

PC Open Date & Time

23 SEP 2020 09:38

PC Close Date & Time

23 SEP 2020 12:08

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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 98.2 °F

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

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

PC Time Stamp	23 SEP 2020 19:06
PC Open Date & Time	23 SEP 2020 13:03
PC Close Date & Time	24 SEP 2020 11:59

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

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

96.1 °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

24 SEP 2020 18:49

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 20:20

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 19:26

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

27 SEP 2020 20:34

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

28 SEP 2020 20:54

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

29 SEP 2020 19:53

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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

23 SEP 2020 10:07

PC Open Date & Time

23 SEP 2020 09:38

PC Close Date & Time

23 SEP 2020 12:08

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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

23 SEP 2020 19:07

PC Open Date & Time

23 SEP 2020 13:03

PC Close Date & Time

24 SEP 2020 11:59

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 18:50

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

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

25 SEP 2020 20:21

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

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

26 SEP 2020 19:27

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

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

27 SEP 2020 20:34

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

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

28 SEP 2020 20:54

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

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

29 SEP 2020 19:53

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 10:07
PC Open Date & Time	23 SEP 2020 09:38
PC Close Date & Time	23 SEP 2020 12:08

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 19:10
PC Open Date & Time	23 SEP 2020 13:03
PC Close Date & Time	24 SEP 2020 11:59

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

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 ☒

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

Yes ☐	
PC Time stamp	24 SEP 2020 18:51
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

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 ☒

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

Yes ☐	
PC Time stamp	25 SEP 2020 20:21
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

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 ☒

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

Yes ☐	
PC Time stamp	26 SEP 2020 19:28
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

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 ☒

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

Yes ☐	
PC Time stamp	27 SEP 2020 20:35
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

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 ☒

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

Yes ☐	
PC Time stamp	28 SEP 2020 20:55
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

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 ☒

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

Yes ☐	
PC Time stamp	29 SEP 2020 19:54
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3802046

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 08 Oct 2020 19:06:29

Generated On: 26 Nov 2020 11:20:44

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3802046

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 08 Oct 2020 19:06:29

Generated On: 26 Nov 2020 11:20:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802046

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 08 Oct 2020 19:06:29

Generated On: 26 Nov 2020 11:20:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3802046

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 08 Oct 2020 19:06:29

Generated On: 26 Nov 2020 11:20:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802046

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3802046

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802046

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	21 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3802046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	21 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	08:11 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 08:11
Temperature (<i>xxx.x</i>)	98.7 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	INFRARED
Pulse (<i>xxx</i>)	67 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3802046

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

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.

US3802046

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 OCT 2020

Collection time (00:00-23:59)

08:22 (24 HR)

Collection date and time (derived)

21 OCT 2020 08:22

US3802046

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

27 OCT 2020 18:27:27

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3802046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

02 NOV 2020 20:15:37

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3802046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

09 NOV 2020 19:26:32

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2020 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2020 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2020 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

17 NOV 2020 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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°F/38°C)	True
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	True
Nausea	True
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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	20 NOV 2020 13:14:10
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2020 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

08 DEC 2020 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2020 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2020 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2020 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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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29 JAN 2021 00:01

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02 FEB 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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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06 APR 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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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13 APR 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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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20 APR 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

Please contact your study clinic immediately. Click below to confirm that you have read this 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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30 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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22 FEB 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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22 MAR 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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29 MAR 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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05 APR 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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12 APR 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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19 APR 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3802046

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3802046

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802046

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

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

US3802046

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:20:44

Date of Contact	13 NOV 2020
Time of Contact	10:25
Date and Time of Contact (derived)	13 NOV 2020 10:25
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 ☐

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:20:44

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	☐

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:20:44

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	13 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	100.2 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)	339 of 2142	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:20:44

	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	☐

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:20:44

	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	☐

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:20:44

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	☐

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:20:44

	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	101 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)	343 of 2142	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:20:44

	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	☒

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:20:44

	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	☐

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:20:44

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	☐

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:20:44

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	15 NOV 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.0 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)	347 of 2142	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:20:44

	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	☐

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:20:44

	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	☐

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:20:44

[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	☐

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:20:44

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	16 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.0 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)	351 of 2142	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:20:44

	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	☐

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:20:44

	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	☐

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:20:44

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	☐

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:20:44

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	17 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.7 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)	355 of 2142	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:20:44

	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	☒

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:20:44

	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	☐

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:20:44

[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	☐

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:20:44

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	18 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.9 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)	359 of 2142	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:20:44

	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	☐

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:20:44

	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	☐

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:20:44

[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	☐

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:20:44

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	19 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.9 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)	363 of 2142	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:20:44

	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	☐

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:20:44

	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	☐

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:20:44

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	☐

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:20:44

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	20 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	99.1 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)	367 of 2142	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:20:44

	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	☐

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:20:44

	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	☐

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:20:44

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	☐

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:20:44

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	21 NOV 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	99 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)	371 of 2142	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:20:44

	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	☐

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:20:44

	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	☐

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:20:44

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	13 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)	1

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:20:44

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date _____

If Yes to either Did subject require any of the following:

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:20:44

Ventilator Support:

High-Flow Oxygen? Yes ☐ No ☒

Start Date _____

End Date _____

Non-Invasive Ventilation? Yes ☐ No ☒

Start Date _____

End Date _____

Mechanical Ventilation? Yes ☐ No ☒

Start Date _____

End Date _____

ECMO? Yes ☐ No ☒

Start Date _____

End Date _____

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐ No ☒

Start Date _____

End Date _____

Evidence of Shock Requires Vasopressors Yes ☐ No ☒

Start Date _____

End Date _____

Acute Renal Dysfunction? Yes ☐ No ☒

Start Date _____

Hepatic Dysfunction? Yes ☐ No ☒

Start Date _____

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:20:44

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐
No ☒

Start Date

End Date

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 09 Sep 2020 18:08:39

Generated On: 26 Nov 2020 11:20:44

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3802046

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 11:20:44

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	15 NOV 2020
Day 5	Yes	17 NOV 2020
Day 7	Yes	19 NOV 2020
Day 9	Yes	21 NOV 2020
Day 14		
Day 21		
Day 28		

US3802046

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

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

US3802046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

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>)	10:32 (24 HR)
Vital Signs Date and Time (derived)	13 NOV 2020 10:32
Height (<i>xxx.x</i>)	ND - Not Done
Weight (<i>xxx.x</i>)	ND - Not Done
Temperature (<i>xxx.x</i>)	100.2 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	INFARED
Pulse (<i>xxx</i>)	82 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	22 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3802046

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

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.

US3802046

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 11:20:44

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

13 NOV 2020

US3802046

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

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 _____

US3802046

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

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)	

US3802046

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

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.

US3802046

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 11:20:44

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

US3802046

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:20:44

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

AEID	USA-US098-2020-MRNA-1273-P30 1000005
Adverse event	SYMPTOMATIC COVID 19
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)	13 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)	
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)	21 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	23 NOV 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	389 of 2142

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

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	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

70 YEAR OLD SUBJECT WHO
BEGAN TO EXPERIENCE
WORSENING SHORTNESS OF
BREATH AND COUGH WITH
COVID19. PRESENTED TO ED
FOR EVALUATION ON
11/21/2020 AND WAS
ADMITTED.
11/21/2020: COMPARED WITH
PREVIOUS ECG AND
UNCHANGED WITHOUT
EVIDENCE OF ACUTE
ISCHEMIA OR ARRHYTHMIA,
CXR:1 VIEW CHEST X-RAY, PER
MY INTERPRETATION:
NORMAL HEART AND
MEDIASTINUM WITHOUT
INFILTRATE OR
PNEUMOTHORAX, NO
EVIDENCE FOR PNEUMONIA OR
PULMONARY EDEMA ON
FRONTAL CHEST RADIOGRAPH

CT ANGIOGRAPHY OF THE
CHEST PERFORMED TO
EVALUATE FOR PULMONARY
EMBOLISM/COVID AND READ
BY RADIOLOGY AS:
"IMPRESSION: NO ACUTE
PULMONARY EMBOLUS OR
AORTIC DISSECTION.
MULTIPLE SUBPLEURAL
MIXED INTERSTITIAL AND
GROUNDGLASS OPACITY IN
BOTH LUNG PREDOMINANTLY
IN THE LUNG BASES,
CONSISTENT WITH THE

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

KNOWN COVID 19 INFECTION."
SUBJECT DID NOT MEET
CRITERIA FOR REMDESIVIR
AND DID NOT REQUIRE ANY
SUPPLEMENTAL OXYGEN.
11/22/2020- 37.1, 88, 125/81,
97-99% ROOM AIR
11/23/2020- 36.7, 70, 18, 114/72,
95-96% ROOM AIR,
DISCHARGED TO HOME,
CLINICALLY IMPROVED.

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

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Sep 2020 18:08:38

Generated On: 26 Nov 2020 11:20:44

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

Yes ☒

No ☐

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

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

Name of Medication	BUSPAR
Prophylaxis	Yes ☐ No ☒
Indication	ANXIETY
Dose per administration	UNKNOWN
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 ☐

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

	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 2005
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	☒

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

Name of Medication	PROZAC
Prophylaxis	Yes ☐ No ☒
Indication	MILD DEPRESSION
Dose per administration	20
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

	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	2005
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	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

Name of Medication	BONIVA
Prophylaxis	Yes ☐ No ☒
Indication	MILD OSTEOPOROSIS
Dose per administration	UNKNOWN
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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

	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 2017
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	☐

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

Name of Medication	PEPCID-FAMOTIDINE
Prophylaxis	Yes ☐ No ☒
Indication	ACID INDIGESTION
Dose per administration	UNKNOWN
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 ☐

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

	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 2000
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)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

Name of Medication	INFLUENZA VACCINE
Prophylaxis	Yes ☒ No ☐
Indication	PREVENT FLU
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	INJECTION
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	YEARLY
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☒

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

	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)	20 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy) 20 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	☐

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

Name of Medication	DEXAMETHASONE
Prophylaxis	Yes ☐ No ☒
Indication	COVID 19 PNA
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 ☐

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

	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)		22 NOV 2020
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	☒

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

Name of Medication	ACETAMINOPHEN
Prophylaxis	Yes ☐ No ☒
Indication	COVID 19
Dose per administration	325
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

	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)		
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	☐

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:20:44

Name of Medication	ASPIRIN
Prophylaxis	Yes ☐ No ☒
Indication	DVT PREVENTION
Dose per administration	81
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 ☐

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:20:44

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)	14 NOV 2020
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 ☒

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:20:44

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ☒
Indication	PAIN
Dose per administration	400
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 ☐

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:20:44

	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)		17 NOV 2020
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)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:20:44

Name of Medication	VITAMIN D
Prophylaxis	Yes ☒ No ☐
Indication	COVID 19
Dose per administration	1000
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 ☐

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:20:44

	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)		14 NOV 2020
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	☒

US3802046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Sep 2020 18:08:38

Generated On: 26 Nov 2020 11:20:44

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3802046

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 09 Sep 2020 18:08:39

Generated On: 26 Nov 2020 11:20:44

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

US3802046

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 09 Sep 2020 18:08:39

Generated On: 26 Nov 2020 11:20:44

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	☐

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

SAEID	USA-US098-2020-MRNA-1273-P301000005
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	JUDITH
Investigator's Last Name	MARTIN
Site Address: Street	3420 FIFTH AVE
Site Address: City	PITTSBURGH
Site Address: State	PA
Site Address: Postal Code	15213
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:20:44

SAEID	USA-US098-2020-MRNA-1273-P301000005
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	JUDITH
Investigator's Last Name	MARTIN
Site Address: Street	3420 FIFTH AVE
Site Address: City	PITTSBURGH
Site Address: State	PA
Site Address: Postal Code	15213
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	16/NOV/2020 20:40
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

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:20:44

SAEID	USA-US098-2020-MRNA-1273-P301000005
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	JUDITH
Investigator's Last Name	MARTIN
Site Address: Street	3420 FIFTH AVE
Site Address: City	PITTSBURGH
Site Address: State	PA
Site Address: Postal Code	15213
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	24/NOV/2020 14:06
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.	True

Audit

US3802046 (Prod: UPMC University Center)

US3802046

Form: Participant Creation

Generated On: 26 Nov 2020 11:20:44

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'US3802046'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 19:05:39

US3802046

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:07:06

US3802046

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '26 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 19:05:40

US3802046

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'Clinic (Clinic)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:07:06

US3802046

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	26 Aug 2020 19:07:06

US3802046

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered (b) (6) 1950'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 19:05:41

US3802046

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[Age](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '70'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:07:17

US3802046

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	26 Aug 2020 19:07:17

US3802046

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '70'	System	26 Aug 2020 19:07:31

US3802046

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

Sex

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'Female (F)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:07:17

US3802046

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[Ethnicity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:07:17

US3802046

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[White](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '1'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:07:17

US3802046

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[Black](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '0'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:07:17

US3802046

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[Asian](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '0'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:07:17

US3802046

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4) (b) (4)	09 Sep 2020 18:08:40
User entered '0'	Lalicia Roman (b) (4) (b) (4)	26 Aug 2020 19:07:17

US3802046

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4) (b) (4)	09 Sep 2020 18:08:40
User entered '0'	Lalicia Roman (b) (4) (b) (4)	26 Aug 2020 19:07:17

US3802046

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[Other](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered '0'	Lalicia Roman (b) (4)	26 Aug 2020 19:07:17
	(b) (4)	

US3802046

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

If race is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4) (b) (4)	09 Sep 2020 18:08:40
User entered empty.	Lalicia Roman (b) (4) (b) (4)	26 Aug 2020 19:07:17

US3802046

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

Unknown

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '0'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:07:17

US3802046

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[Not reported](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4) (b) (4)	09 Sep 2020 18:08:40
User entered '0'	Lalicia Roman (b) (4) (b) (4)	26 Aug 2020 19:07:17

US3802046

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:20:44

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered '26 Aug 2020'	Lalicia Roman (b) (4)	26 Aug 2020 19:07:31
	(b) (4)	

US3802046

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	26 Aug 2020 19:07:31

US3802046

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '2020'	System	26 Aug 2020 19:07:31

US3802046

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:20:44

[Protocol Version](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'Amendment 2 (2)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:07:31

US3802046

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4) (b) (4)	09 Sep 2020 18:08:40
User entered 'Yes (Y)'	Lalicia Roman (b) (4) (b) (4)	26 Aug 2020 19:07:31

US3802046

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4) (b) (4)	09 Sep 2020 18:08:40
User entered empty.	Lalicia Roman (b) (4) (b) (4)	26 Aug 2020 19:07:31

US3802046

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:20:44

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered empty.	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:07:31

US3802046

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:20:44

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4) (b) (4)	09 Sep 2020 18:08:40
User entered 'No (N)'	Lalicia Roman (b) (4) (b) (4)	26 Aug 2020 19:07:31

US3802046

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:20:44

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 19:05:40

US3802046

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:20:44

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 19:07:35

US3802046

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:07:35

US3802046

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:20:44

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:16:39

US3802046

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:20:44

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	27 Aug 2020 18:14:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:14:09
Data point term sent to Coder	System	26 Aug 2020 19:49:28
User entered 'allergies sulfa'	Lalicia Roman (b) (4) (b) (4)	26 Aug 2020 19:49:04

US3802046

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'UN UNK 2000'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:49:04

US3802046

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '0'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:49:04

US3802046

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:20:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:49:04

US3802046

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered empty.	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:49:04

US3802046

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:20:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '0'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:49:04

US3802046

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	26 Aug 2020 19:49:04

US3802046

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '2000'	System	26 Aug 2020 19:49:04

US3802046

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 19:49:04

US3802046

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 19:49:04

US3802046

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:20:44

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergy to antibiotic - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 05:06:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 05:06:42
User signature succeeded.	Judith Martin (b) (4) (b) (4)	09 Sep 2020 18:08:40
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to antibiotics - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:13:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:13:58
Data point term sent to Coder	System	26 Aug 2020 19:49:29
User entered 'allergies cephalosporin'	Lalicia Roman (b) (4) (b) (4)	26 Aug 2020 19:49:27

US3802046

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'UN UNK 1980'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:49:27

US3802046

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '0'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:49:27

US3802046

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:20:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:49:27

US3802046

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered empty.	Lalicia Roman (b) (4)	26 Aug 2020 19:49:27
	(b) (4)	

US3802046

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:20:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4) (b) (4)	09 Sep 2020 18:08:40
User entered '0'	Lalicia Roman (b) (4) (b) (4)	26 Aug 2020 19:49:27

US3802046

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Jan 1980'	System	26 Aug 2020 19:49:27

US3802046

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '1980'	System	26 Aug 2020 19:49:27

US3802046

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 19:49:27

US3802046

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 19:49:27

US3802046

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:20:44

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 18:12:02
Data point term sent to Coder	(b) (4)	
User entered 'depression'	System	27 Aug 2020 18:12:02
	System	26 Aug 2020 19:50:30
	Lalicia Roman (b) (4)	26 Aug 2020 19:49:55
	(b) (4)	

US3802046

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'UN UNK 2005'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:49:55

US3802046

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '0'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:49:55

US3802046

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:20:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:49:55

US3802046

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered empty.	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:49:55

US3802046

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:20:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '0'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:49:55

US3802046

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	26 Aug 2020 19:49:55

US3802046

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '2005'	System	26 Aug 2020 19:49:55

US3802046

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 19:49:55

US3802046

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 19:49:55

US3802046

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:20:44

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	27 Aug 2020 18:12:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:12:02
Data point term sent to Coder	System	26 Aug 2020 19:50:31
User entered 'osteoporosis'	Lalicia Roman (b) (4) (b) (4)	26 Aug 2020 19:50:31

US3802046

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'UN UNK 2017'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:50:31

US3802046

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered '0'	Lalicia Roman (b) (4)	26 Aug 2020 19:50:31
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:20:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:50:31

US3802046

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered empty.	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:50:31

US3802046

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:20:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '0'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:50:31

US3802046

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	26 Aug 2020 19:50:31

US3802046

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '2017'	System	26 Aug 2020 19:50:31

US3802046

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 19:50:31

US3802046

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 19:50:31

US3802046

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:20:44

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 15:15:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	07 Oct 2020 15:15:56
Data point term sent to Coder	System	07 Oct 2020 14:23:31
User entered 'Post menopausal'	Melissa Andrasko (b) (4)	07 Oct 2020 14:23:25

US3802046

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	Melissa Andrasko (b) (4)	07 Oct 2020 14:23:25

US3802046

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Melissa Andrasko (b) (4)	07 Oct 2020 14:23:25

US3802046

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:20:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 19:42:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 19:42:03
User entered 'Yes (Y)' reason for change: Data Entry Error	Emily Carney (b) (4) (b) (4)	20 Oct 2020 19:42:03
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 14:23:25
User entered empty.	Melissa Andrasko (b) (4) (b) (4)	07 Oct 2020 14:23:25

US3802046

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	Melissa Andrasko (b) (4)	07 Oct 2020 14:23:25

US3802046

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:20:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0' reason for change: Data Entry Error	Emily Carney (b) (4)	20 Oct 2020 19:42:03
User entered '1'	(b) (4) Melissa Andrasko (b) (4)	07 Oct 2020 14:23:25

US3802046

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 14:23:25

US3802046

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 14:23:25

US3802046

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 14:23:25

US3802046

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 14:23:25

US3802046

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:20:44

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 19:40:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 19:40:42
Data point term sent to Coder	System	20 Oct 2020 19:39:38
User entered 'Anxiety'	Emily Carney (b) (4)	20 Oct 2020 19:39:13
	(b) (4)	

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	Emily Carney (b) (4) (b) (4)	20 Oct 2020 19:39:13

US3802046

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Emily Carney (b) (4) (b) (4)	20 Oct 2020 19:39:13

US3802046

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:20:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Carney (b) (4) (b) (4)	20 Oct 2020 19:39:13

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	Emily Carney (b) (4) (b) (4)	20 Oct 2020 19:39:13

US3802046

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:20:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Emily Carney (b) (4) (b) (4)	20 Oct 2020 19:39:13

US3802046

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 19:39:13

US3802046

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 19:39:13

US3802046

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 19:39:13

US3802046

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 19:39:13

US3802046

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:20:44

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Acid indigestion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 19:41:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 19:41:45
Data point term sent to Coder	System	20 Oct 2020 19:40:40
User entered 'Acid indigestion'	Emily Carney (b) (4) (b) (4)	20 Oct 2020 19:40:14

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	Emily Carney (b) (4) (b) (4)	20 Oct 2020 19:40:14

US3802046

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Emily Carney (b) (4) (b) (4)	20 Oct 2020 19:40:14

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:20:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Carney (b) (4) (b) (4)	20 Oct 2020 19:40:14

US3802046

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	Emily Carney (b) (4) (b) (4)	20 Oct 2020 19:40:14

US3802046

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:20:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Emily Carney (b) (4) (b) (4)	20 Oct 2020 19:40:14

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 19:40:14

US3802046

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 19:40:14

US3802046

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 19:40:14

US3802046

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 19:40:14

US3802046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:46:39

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered '26 Aug 2020'	Lalicia Roman (b) (4)	26 Aug 2020 19:46:39
	(b) (4)	

US3802046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '15:19'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:46:39

US3802046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '26 Aug 2020 15:19'	System	26 Aug 2020 19:46:39

US3802046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

Height (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered '157' cm	Lalicia Roman (b) (4)	26 Aug 2020 19:46:39
	(b) (4)	
DataPoint set to visible.	System	26 Aug 2020 19:07:35

US3802046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered '133' lb	Lalicia Roman (b) (4)	26 Aug 2020 19:46:39
	(b) (4)	
DataPoint set to visible.	System	26 Aug 2020 19:07:35

US3802046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '24.52617'	System	17 Sep 2020 00:04:13
User entered '24.5'	System	26 Aug 2020 19:46:39
DataPoint set to visible.	System	26 Aug 2020 19:07:35

US3802046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	26 Aug 2020 19:46:39
DataPoint set to visible.	System	26 Aug 2020 19:07:35

US3802046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered '97.5' F	Lalicia Roman (b) (4)	26 Aug 2020 19:46:39
	(b) (4)	

US3802046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'Other (Other)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:46:39

US3802046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'infrared'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:46:39

US3802046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '72'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:46:39

US3802046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	26 Aug 2020 19:46:39

US3802046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4) (b) (4)	09 Sep 2020 18:08:40
User entered '16'	Lalicia Roman (b) (4) (b) (4)	26 Aug 2020 19:46:39

US3802046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	26 Aug 2020 19:46:39

US3802046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '137'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:46:39

US3802046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Aug 2020 19:46:39

US3802046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '88'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:46:39

US3802046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Aug 2020 19:46:39

US3802046

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:07:47

US3802046

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered '26 Aug 2020'	Lalicia Roman (b) (4)	26 Aug 2020 19:07:47
	(b) (4)	

US3802046

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:20:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered '26 Aug 2020'	Lalicia Roman (b) (4)	26 Aug 2020 19:08:01
	(b) (4)	

US3802046

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:08:01

US3802046

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:20:44

If No, what is the reason?

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 09:32:14
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'done' (Site from DM).	Melissa Andrasko (b) (4)	07 Oct 2020 14:23:27
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 06:09:19
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Lalicia Roman (b) (4)	26 Aug 2020 19:08:01

US3802046

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered empty.	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:08:01

US3802046

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered empty.	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:08:01
	(b) (4)	

US3802046

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:20:44

Date of surgery unknown

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '0'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:08:01

US3802046

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered empty.	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:08:01
	(b) (4)	

US3802046

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:20:44

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '1'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:08:01

US3802046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:47:12

US3802046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:47:12
	(b) (4)	

US3802046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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 signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:47:12
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:47:12
	(b) (4)	

US3802046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:47:12

US3802046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:47:12

US3802046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:47:12
	(b) (4)	

US3802046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:47:12
	(b) (4)	

US3802046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:47:12
	(b) (4)	

US3802046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:47:12
	(b) (4)	

US3802046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:47:12
	(b) (4)	

US3802046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

[Other](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'No (N)'	Lalicia Roman (b) (4)	26 Aug 2020 19:47:12
	(b) (4)	

US3802046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

[Specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered empty.	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:47:12

US3802046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

No Risk Identified

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '0'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:47:12

US3802046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '0'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:47:12

US3802046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '0'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:47:12
	(b) (4)	

US3802046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered '0'	Lalicia Roman (b) (4)	26 Aug 2020 19:47:12
	(b) (4)	

US3802046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '0'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:47:12
	(b) (4)	

US3802046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '1'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:47:12

US3802046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

[Other](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4) (b) (4)	09 Sep 2020 18:08:40
User entered '0'	Lalicia Roman (b) (4) (b) (4)	26 Aug 2020 19:47:12

US3802046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

[Specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4) (b) (4)	09 Sep 2020 18:08:40
User entered empty.	Lalicia Roman (b) (4) (b) (4)	26 Aug 2020 19:47:12

US3802046

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:17:08

US3802046

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '26 Aug 2020'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:17:08

US3802046

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'Clinic (Clinic)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:17:08

US3802046

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	26 Aug 2020 19:17:08

US3802046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '26 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 19:19:43

US3802046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:20:44

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '188343'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 19:19:43

US3802046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 19:19:43

US3802046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:17:20
	(b) (4)	

US3802046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:17:20
	(b) (4)	

US3802046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:17:20
	(b) (4)	

US3802046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4) (b) (4)	09 Sep 2020 18:08:40
User entered 'No (N)'	Lalicia Roman (b) (4) (b) (4)	26 Aug 2020 19:17:20

US3802046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:20:44

[Liver Disease](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:17:20

US3802046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 22:08:01
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'entered' (Site from DM).	Jennifer Nagg (b) (4)	20 Nov 2020 21:23:09
User entered 'No (N)'	Jennifer Nagg (b) (4)	20 Nov 2020 21:23:00
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 20:55:25
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:47:15
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:06:57

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:20:44

Height

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '157' cm	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 20:51:32
	(b) (4)	

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:20:44

Weight

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '133' lb	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 20:51:32

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:20:44

[Height](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered '157' cm	Lalicia Roman (b) (4)	26 Aug 2020 20:51:32
	(b) (4)	

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:20:44

[Weight](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '133' lb	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 20:51:32

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Lalicia Roman (b) (4) (b) (4)	26 Aug 2020 20:51:32

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 20:51:32

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '26 Aug 2020'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 20:51:32
	(b) (4)	

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4) (b) (4)	09 Sep 2020 18:08:40
User entered '15:19'	Lalicia Roman (b) (4) (b) (4)	26 Aug 2020 20:51:32

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '26 Aug 2020 15:19'	System	26 Aug 2020 20:51:32

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered '97.5' F	Lalicia Roman (b) (4)	26 Aug 2020 20:51:32
	(b) (4)	

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'Other (Other)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 20:51:32

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'infrared'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 20:51:32

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '72'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 20:51:32

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	26 Aug 2020 20:51:32

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4) (b) (4)	09 Sep 2020 18:08:40
User entered '16'	Lalicia Roman (b) (4) (b) (4)	26 Aug 2020 20:51:32

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	26 Aug 2020 20:51:32

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '137'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 20:51:32

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Aug 2020 20:51:32

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '88'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 20:51:32

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Aug 2020 20:51:32

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:20:44

Height

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '157' cm	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 20:51:32

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:20:44

[Weight](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '133' lb	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 20:51:32

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Lalicia Roman (b) (4) (b) (4)	26 Aug 2020 20:51:32

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 20:51:32

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '26 Aug 2020'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 20:51:32
	(b) (4)	

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4) (b) (4)	09 Sep 2020 18:08:40
User entered '16:26'	Lalicia Roman (b) (4) (b) (4)	26 Aug 2020 20:51:32

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '26 Aug 2020 16:26'	System	26 Aug 2020 20:51:32

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered '97.7' F	Lalicia Roman (b) (4)	26 Aug 2020 20:51:32
	(b) (4)	

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'Other (Other)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 20:51:32

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'infrared'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 20:51:32

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '65'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 20:51:32

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	26 Aug 2020 20:51:32

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4) (b) (4)	09 Sep 2020 18:08:40
User entered '18'	Lalicia Roman (b) (4) (b) (4)	26 Aug 2020 20:51:32

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	26 Aug 2020 20:51:32

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '130'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 20:51:32
	(b) (4)	

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Aug 2020 20:51:32

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '76'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 20:51:32

US3802046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Aug 2020 20:51:32

US3802046

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:21:17

US3802046

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered '26 Aug 2020'	Lalicia Roman (b) (4)	26 Aug 2020 19:21:17
	(b) (4)	

US3802046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 20:00:58

US3802046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4) (b) (4)	09 Sep 2020 18:08:40
User entered empty.	Lalicia Roman (b) (4) (b) (4)	26 Aug 2020 20:00:58

US3802046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4) (b) (4)	09 Sep 2020 18:08:40
User entered empty.	Lalicia Roman (b) (4) (b) (4)	26 Aug 2020 20:00:58

US3802046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 20:00:58

US3802046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered '26 Aug 2020'	Lalicia Roman (b) (4)	26 Aug 2020 20:00:58
	(b) (4)	

US3802046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '15:54'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 20:00:58
	(b) (4)	

US3802046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '26 Aug 2020 15:54'	System	26 Aug 2020 20:00:58

US3802046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'Left Arm (LEFT ARM)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 20:00:58

US3802046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	26 Aug 2020 20:00:58

US3802046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 20:00:58

US3802046

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:47:52

US3802046

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered '26 Aug 2020'	Lalicia Roman (b) (4)	26 Aug 2020 19:47:52
	(b) (4)	

US3802046

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4) (b) (4)	09 Sep 2020 18:08:40
User entered '15:31'	Lalicia Roman (b) (4) (b) (4)	26 Aug 2020 19:47:52

US3802046

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '26 Aug 2020 15:31'	System	26 Aug 2020 19:47:52

US3802046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:20:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered '26 Aug 2020'	Lalicia Roman (b) (4)	26 Aug 2020 19:48:21
	(b) (4)	

US3802046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:20:44

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Lalicia Roman (b) (4) (b) (4)	26 Aug 2020 19:48:21

US3802046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:20:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:48:21

US3802046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:20:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered '15:27'	Lalicia Roman (b) (4)	26 Aug 2020 19:48:21
	(b) (4)	

US3802046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '26 Aug 2020 15:27'	System	26 Aug 2020 19:48:21

US3802046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:20:44

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Lalicia Roman (b) (4) (b) (4)	26 Aug 2020 19:48:21

US3802046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:20:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:48:21
	(b) (4)	

US3802046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:20:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered empty.	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:48:21

US3802046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 19:48:21

US3802046

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	26 Aug 2020 19:48:25

US3802046

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 19:48:25

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:00:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-26T16:36:48', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '1e8f538c-d751-4e56-a984-b3cae1245b5c'	System	26 Aug 2020 20:37:16
User entered 'Yes (Y)'	System	26 Aug 2020 20:37:16

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-26T16:37:01', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '1e8f538c-d751-4e56-a984-b3cae1245b5c' User entered '97.7'	System	26 Aug 2020 20:37:16

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-26T16:37:05', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '1e8f538c-d751-4e56-a984-b3cae1245b5c'	System	26 Aug 2020 20:37:16
User entered 'No (N)'	System	26 Aug 2020 20:37:16

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-26T16:37:14', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '1e8f538c-d751-4e56-a984-b3cae1245b5c'	System	26 Aug 2020 20:37:16
User entered '26 Aug 2020 16:37'	System	26 Aug 2020 20:37:16

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 16:14'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 18:44'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:00:58
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-26T20:28:38', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '5b95eef4-85c5-4928-a4cc-4018636f347d'	System	27 Aug 2020 00:29:08
User entered 'Yes (Y)'	System	27 Aug 2020 00:29:08

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-26T20:28:47', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '5b95eef4-85c5-4928-a4cc-4018636f347d'	System	27 Aug 2020 00:29:08
User entered '97.0'	System	27 Aug 2020 00:29:08

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-26T20:28:51', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '5b95eef4-85c5-4928-a4cc-4018636f347d'	System	27 Aug 2020 00:29:08
User entered 'No (N)'	System	27 Aug 2020 00:29:08

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-26T20:29:03', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '5b95eef4-85c5-4928-a4cc-4018636f347d'	System	27 Aug 2020 00:29:08
User entered '26 Aug 2020 20:29'	System	27 Aug 2020 00:29:08

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 19:39'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:00:58
User entered 'Day 2'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-27T19:06:16', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'c196f2f0-6825-4c89-bea1-a2ee1f8d1620'	System	27 Aug 2020 23:07:20
User entered 'Yes (Y)'	System	27 Aug 2020 23:07:20

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-27T19:07:04', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'c196f2f0-6825-4c89-bea1-a2ee1f8d1620'	System	27 Aug 2020 23:07:20
User entered '97.9'	System	27 Aug 2020 23:07:20

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-27T19:07:10', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'c196f2f0-6825-4c89-bea1-a2ee1f8d1620'	System	27 Aug 2020 23:07:20
User entered 'No (N)'	System	27 Aug 2020 23:07:20

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-27T19:07:15', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'c196f2f0-6825-4c89-bea1-a2ee1f8d1620'	System	27 Aug 2020 23:07:20
User entered '27 Aug 2020 19:07'	System	27 Aug 2020 23:07:20

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:00:58
User entered 'Day 3'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-28T19:46:27', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '06ca0155-1998-496f-8abe-d155f08f4c84'	System	28 Aug 2020 23:46:51
User entered 'Yes (Y)'	System	28 Aug 2020 23:46:51

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-28T19:46:35', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '06ca0155-1998-496f-8abe-d155f08f4c84'	System	28 Aug 2020 23:46:51
User entered '97.7'	System	28 Aug 2020 23:46:51

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-28T19:46:40', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '06ca0155-1998-496f-8abe-d155f08f4c84'	System	28 Aug 2020 23:46:51
User entered 'No (N)'	System	28 Aug 2020 23:46:51

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-28T19:46:46', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '06ca0155-1998-496f-8abe-d155f08f4c84'	System	28 Aug 2020 23:46:51
User entered '28 Aug 2020 19:46'	System	28 Aug 2020 23:46:51

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:00:58
User entered 'Day 4'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-29T22:06:57', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '1d06763c-619f-4282-a5a8-b14ac208d698'	System	30 Aug 2020 02:07:13
User entered 'Yes (Y)'	System	30 Aug 2020 02:07:13

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-29T22:07:04', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '1d06763c-619f-4282-a5a8-b14ac208d698'	System	30 Aug 2020 02:07:13
User entered '97.2'	System	30 Aug 2020 02:07:13

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-29T22:07:07', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '1d06763c-619f-4282-a5a8-b14ac208d698'	System	30 Aug 2020 02:07:13
User entered 'No (N)'	System	30 Aug 2020 02:07:13

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-29T22:07:11', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '1d06763c-619f-4282-a5a8-b14ac208d698'	System	30 Aug 2020 02:07:13
User entered '29 Aug 2020 22:07'	System	30 Aug 2020 02:07:13

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:00:58
User entered 'Day 5'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-30T20:48:34', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '66ecbdb4-1979-4c9b-89a3-397c70fa7129'	System	31 Aug 2020 00:49:09
User entered 'Yes (Y)'	System	31 Aug 2020 00:49:09

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-30T20:49:00', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '66ecbdb4-1979-4c9b-89a3-397c70fa7129'	System	31 Aug 2020 00:49:09
User entered '97.7'	System	31 Aug 2020 00:49:09

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-30T20:49:04', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '66ecbdb4-1979-4c9b-89a3-397c70fa7129'	System	31 Aug 2020 00:49:09
User entered 'No (N)'	System	31 Aug 2020 00:49:09

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-30T20:49:07', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '66ecbdb4-1979-4c9b-89a3-397c70fa7129'	System	31 Aug 2020 00:49:09
User entered '30 Aug 2020 20:49'	System	31 Aug 2020 00:49:09

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:00:58
User entered 'Day 6'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-31T21:22:05', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '6485da90-957e-4511-a865-0eb6463d9ad2'	System	01 Sep 2020 01:22:23
User entered 'Yes (Y)'	System	01 Sep 2020 01:22:23

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-31T21:22:12', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '6485da90-957e-4511-a865-0eb6463d9ad2'	System	01 Sep 2020 01:22:23
User entered '97.4'	System	01 Sep 2020 01:22:23

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-31T21:22:15', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '6485da90-957e-4511-a865-0eb6463d9ad2'	System	01 Sep 2020 01:22:23
User entered 'No (N)'	System	01 Sep 2020 01:22:23

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-31T21:22:19', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '6485da90-957e-4511-a865-0eb6463d9ad2'	System	01 Sep 2020 01:22:23
User entered '31 Aug 2020 21:22'	System	01 Sep 2020 01:22:23

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:00:58
User entered 'Day 7'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-01T20:11:34', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '0990bcb2-bdfa-4822-88b4-0485d00d292f'	System	02 Sep 2020 00:12:49
User entered 'Yes (Y)'	System	02 Sep 2020 00:12:49

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-01T20:12:37', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '0990bcb2-bdfa-4822-88b4-0485d00d292f' User entered '97.7'	System	02 Sep 2020 00:12:49

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-01T20:12:41', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '0990bcb2-bdfa-4822-88b4-0485d00d292f'	System	02 Sep 2020 00:12:49
User entered 'No (N)'	System	02 Sep 2020 00:12:49

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-01T20:12:46', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '0990bcb2-bdfa-4822-88b4-0485d00d292f'	System	02 Sep 2020 00:12:49
User entered '01 Sep 2020 20:12'	System	02 Sep 2020 00:12:49

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:00:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-26T16:37:47', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '257a235b-6a0e-4d55-be34-6fe7c282c702'	System	26 Aug 2020 20:38:18
User entered 'None (1)'	System	26 Aug 2020 20:38:18

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-26T16:37:50', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '257a235b-6a0e-4d55-be34-6fe7c282c702'	System	26 Aug 2020 20:38:18
User entered 'No (N)'	System	26 Aug 2020 20:38:18

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-26T16:37:55', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '257a235b-6a0e-4d55-be34-6fe7c282c702'	System	26 Aug 2020 20:38:18
User entered 'No (N)'	System	26 Aug 2020 20:38:18

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-26T16:38:06', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '257a235b-6a0e-4d55-be34-6fe7c282c702'	System	26 Aug 2020 20:38:18
User entered 'None (1)'	System	26 Aug 2020 20:38:18

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-26T16:38:16', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '257a235b-6a0e-4d55-be34-6fe7c282c702'	System	26 Aug 2020 20:38:18
User entered '26 Aug 2020 16:38'	System	26 Aug 2020 20:38:18

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 16:14'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 18:44'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:00:58
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-26T20:29:15', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '76f5d153-f582-4de1-b25c-208a3725a238'	System	27 Aug 2020 00:30:10
User entered 'None (1)'	System	27 Aug 2020 00:30:10

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-26T20:29:37', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '76f5d153-f582-4de1-b25c-208a3725a238'	System	27 Aug 2020 00:30:10
User entered 'No (N)'	System	27 Aug 2020 00:30:10

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-26T20:29:44', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '76f5d153-f582-4de1-b25c-208a3725a238'	System	27 Aug 2020 00:30:10
User entered 'No (N)'	System	27 Aug 2020 00:30:10

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-26T20:29:59', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '76f5d153-f582-4de1-b25c-208a3725a238'	System	27 Aug 2020 00:30:10
User entered 'None (1)'	System	27 Aug 2020 00:30:10

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-26T20:30:07', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '76f5d153-f582-4de1-b25c-208a3725a238'	System	27 Aug 2020 00:30:10
User entered '26 Aug 2020 20:30'	System	27 Aug 2020 00:30:10

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 19:39'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:00:58
User entered 'Day 2'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-27T19:08:05', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '4b5ebade-4582-4ae3-8188-82267b4bf953'	System	27 Aug 2020 23:08:26
User entered 'None (1)'	System	27 Aug 2020 23:08:26

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-27T19:08:10', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '4b5ebade-4582-4ae3-8188-82267b4bf953'	System	27 Aug 2020 23:08:26
User entered 'No (N)'	System	27 Aug 2020 23:08:26

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-27T19:08:14', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '4b5ebade-4582-4ae3-8188-82267b4bf953'	System	27 Aug 2020 23:08:26
User entered 'No (N)'	System	27 Aug 2020 23:08:26

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-27T19:08:19', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '4b5ebade-4582-4ae3-8188-82267b4bf953'	System	27 Aug 2020 23:08:26
User entered 'None (1)'	System	27 Aug 2020 23:08:26

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-27T19:08:23', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '4b5ebade-4582-4ae3-8188-82267b4bf953'	System	27 Aug 2020 23:08:26
User entered '27 Aug 2020 19:08'	System	27 Aug 2020 23:08:26

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:00:58
User entered 'Day 3'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-28T19:47:00', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '7f69b300-7d94-4efc-8d86-e3bf1ecca572'	System	28 Aug 2020 23:47:35
User entered 'None (1)'	System	28 Aug 2020 23:47:35

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-28T19:47:10', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '7f69b300-7d94-4efc-8d86-e3bf1ecca572'	System	28 Aug 2020 23:47:35
User entered 'No (N)'	System	28 Aug 2020 23:47:35

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-28T19:47:18', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '7f69b300-7d94-4efc-8d86-e3bf1ecca572'	System	28 Aug 2020 23:47:35
User entered 'No (N)'	System	28 Aug 2020 23:47:35

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-28T19:47:24', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '7f69b300-7d94-4efc-8d86-e3bf1ecca572'	System	28 Aug 2020 23:47:35
User entered 'None (1)'	System	28 Aug 2020 23:47:35

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-28T19:47:33', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '7f69b300-7d94-4efc-8d86-e3bf1ecca572'	System	28 Aug 2020 23:47:35
User entered '28 Aug 2020 19:47'	System	28 Aug 2020 23:47:35

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:00:58
User entered 'Day 4'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-29T22:07:17', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '776ff996-e762-4f7d-841e-f88032a7891a'	System	30 Aug 2020 02:07:43
User entered 'None (1)'	System	30 Aug 2020 02:07:43

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-29T22:07:20', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '776ff996-e762-4f7d-841e-f88032a7891a'	System	30 Aug 2020 02:07:43
User entered 'No (N)'	System	30 Aug 2020 02:07:43

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-29T22:07:28', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '776ff996-e762-4f7d-841e-f88032a7891a'	System	30 Aug 2020 02:07:43
User entered 'No (N)'	System	30 Aug 2020 02:07:43

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-29T22:07:33', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '776ff996-e762-4f7d-841e-f88032a7891a'	System	30 Aug 2020 02:07:43
User entered 'None (1)'	System	30 Aug 2020 02:07:43

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-29T22:07:39', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '776ff996-e762-4f7d-841e-f88032a7891a'	System	30 Aug 2020 02:07:43
User entered '29 Aug 2020 22:07'	System	30 Aug 2020 02:07:43

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:00:58
User entered 'Day 5'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-30T20:49:12', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'cb1eeb49-f17a-4a76-9128-16abe160be60'	System	31 Aug 2020 00:49:26
User entered 'None (1)'	System	31 Aug 2020 00:49:26

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-30T20:49:15', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'cb1eeb49-f17a-4a76-9128-16abe160be60'	System	31 Aug 2020 00:49:26
User entered 'No (N)'	System	31 Aug 2020 00:49:26

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-30T20:49:18', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'cb1eeb49-f17a-4a76-9128-16abe160be60'	System	31 Aug 2020 00:49:26
User entered 'No (N)'	System	31 Aug 2020 00:49:26

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-30T20:49:20', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'cb1eeb49-f17a-4a76-9128-16abe160be60'	System	31 Aug 2020 00:49:26
User entered 'None (1)'	System	31 Aug 2020 00:49:26

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-30T20:49:23', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'cb1eeb49-f17a-4a76-9128-16abe160be60'	System	31 Aug 2020 00:49:26
User entered '30 Aug 2020 20:49'	System	31 Aug 2020 00:49:26

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:00:58
User entered 'Day 6'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-31T21:22:26', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '2df4c899-aa82-4577-a8a3-c6333c1638ea' User entered 'None (1)'	System	01 Sep 2020 01:22:39
	System	01 Sep 2020 01:22:39

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-31T21:22:29', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '2df4c899-aa82-4577-a8a3-c6333c1638ea' User entered 'No (N)'	System	01 Sep 2020 01:22:39

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-31T21:22:31', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '2df4c899-aa82-4577-a8a3-c6333c1638ea' User entered 'No (N)'	System	01 Sep 2020 01:22:39
	System	01 Sep 2020 01:22:39

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-31T21:22:34', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '2df4c899-aa82-4577-a8a3-c6333c1638ea' User entered 'None (1)'	System	01 Sep 2020 01:22:39
	System	01 Sep 2020 01:22:39

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-31T21:22:37', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '2df4c899-aa82-4577-a8a3-c6333c1638ea' User entered '31 Aug 2020 21:22'	System	01 Sep 2020 01:22:39
	System	01 Sep 2020 01:22:39

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:00:58
User entered 'Day 7'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-01T20:12:51', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '7da1d566-3f9f-485c-8e45-62456ba32e5c'	System	02 Sep 2020 00:13:07
User entered 'None (1)'	System	02 Sep 2020 00:13:07

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-01T20:12:54', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '7da1d566-3f9f-485c-8e45-62456ba32e5c'	System	02 Sep 2020 00:13:07
User entered 'No (N)'	System	02 Sep 2020 00:13:07

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-01T20:12:59', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '7da1d566-3f9f-485c-8e45-62456ba32e5c'	System	02 Sep 2020 00:13:07
User entered 'No (N)'	System	02 Sep 2020 00:13:07

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-01T20:13:01', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '7da1d566-3f9f-485c-8e45-62456ba32e5c'	System	02 Sep 2020 00:13:07
User entered 'None (1)'	System	02 Sep 2020 00:13:07

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-01T20:13:04', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '7da1d566-3f9f-485c-8e45-62456ba32e5c'	System	02 Sep 2020 00:13:07
User entered '01 Sep 2020 20:13'	System	02 Sep 2020 00:13:07

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:00:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-26T16:38:25', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '37a6de31-cc9d-4409-b725-eeecb32a1893'	System	26 Aug 2020 20:38:52
User entered 'None (0)'	System	26 Aug 2020 20:38:52

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-26T16:38:29', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '37a6de31-cc9d-4409-b725-eeecb32a1893'	System	26 Aug 2020 20:38:52
User entered 'None (0)'	System	26 Aug 2020 20:38:52

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-26T16:38:32', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '37a6de31-cc9d-4409-b725-eeecb32a1893'	System	26 Aug 2020 20:38:52
User entered 'None (0)'	System	26 Aug 2020 20:38:52

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-26T16:38:35', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '37a6de31-cc9d-4409-b725-eeecb32a1893'	System	26 Aug 2020 20:38:52
User entered 'None (0)'	System	26 Aug 2020 20:38:52

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-26T16:38:38', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '37a6de31-cc9d-4409-b725-eeecb32a1893'	System	26 Aug 2020 20:38:52
User entered 'None (0)'	System	26 Aug 2020 20:38:52

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-26T16:38:41', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '37a6de31-cc9d-4409-b725-eeecb32a1893'	System	26 Aug 2020 20:38:52
User entered 'None (0)'	System	26 Aug 2020 20:38:52

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-26T16:38:45', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '37a6de31-cc9d-4409-b725-eeecb32a1893'	System	26 Aug 2020 20:38:52
User entered 'No (N)'	System	26 Aug 2020 20:38:52

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-26T16:38:50', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '37a6de31-cc9d-4409-b725-eeecb32a1893'	System	26 Aug 2020 20:38:52
User entered '26 Aug 2020 16:38'	System	26 Aug 2020 20:38:52

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 16:14'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 18:44'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:00:58
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-26T20:30:16', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '17fb2f5d-642d-47e0-8533-59c04813eab4'	System	27 Aug 2020 00:31:08
User entered 'None (0)'	System	27 Aug 2020 00:31:08

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-26T20:30:25', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '17fb2f5d-642d-47e0-8533-59c04813eab4'	System	27 Aug 2020 00:31:08
User entered 'None (0)'	System	27 Aug 2020 00:31:08

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-26T20:30:36', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '17fb2f5d-642d-47e0-8533-59c04813eab4'	System	27 Aug 2020 00:31:08
User entered 'None (0)'	System	27 Aug 2020 00:31:08

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-26T20:30:41', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '17fb2f5d-642d-47e0-8533-59c04813eab4'	System	27 Aug 2020 00:31:08
User entered 'None (0)'	System	27 Aug 2020 00:31:08

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-26T20:30:47', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '17fb2f5d-642d-47e0-8533-59c04813eab4'	System	27 Aug 2020 00:31:08
User entered 'None (0)'	System	27 Aug 2020 00:31:08

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-26T20:30:53', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '17fb2f5d-642d-47e0-8533-59c04813eab4'	System	27 Aug 2020 00:31:08
User entered 'None (0)'	System	27 Aug 2020 00:31:08

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-26T20:31:01', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '17fb2f5d-642d-47e0-8533-59c04813eab4'	System	27 Aug 2020 00:31:08
User entered 'No (N)'	System	27 Aug 2020 00:31:08

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-26T20:31:06', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '17fb2f5d-642d-47e0-8533-59c04813eab4'	System	27 Aug 2020 00:31:08
User entered '26 Aug 2020 20:31'	System	27 Aug 2020 00:31:08

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 19:39'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:00:58
User entered 'Day 2'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-27T19:07:25', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'e35dfa67-5ed5-4eac-b7f2-eb3230f21222'	System	27 Aug 2020 23:08:02
User entered 'None (0)'	System	27 Aug 2020 23:08:02

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-27T19:07:30', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'e35dfa67-5ed5-4eac-b7f2-eb3230f21222'	System	27 Aug 2020 23:08:02
User entered 'None (0)'	System	27 Aug 2020 23:08:02

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-27T19:07:34', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'e35dfa67-5ed5-4eac-b7f2-eb3230f21222'	System	27 Aug 2020 23:08:02
User entered 'None (0)'	System	27 Aug 2020 23:08:02

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-27T19:07:38', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'e35dfa67-5ed5-4eac-b7f2-eb3230f21222'	System	27 Aug 2020 23:08:02
User entered 'None (0)'	System	27 Aug 2020 23:08:02

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-27T19:07:42', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'e35dfa67-5ed5-4eac-b7f2-eb3230f21222'	System	27 Aug 2020 23:08:02
User entered 'None (0)'	System	27 Aug 2020 23:08:02

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-27T19:07:47', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'e35dfa67-5ed5-4eac-b7f2-eb3230f21222'	System	27 Aug 2020 23:08:02
User entered 'None (0)'	System	27 Aug 2020 23:08:02

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-27T19:07:54', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'e35dfa67-5ed5-4eac-b7f2-eb3230f21222'	System	27 Aug 2020 23:08:02
User entered 'No (N)'	System	27 Aug 2020 23:08:02

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-27T19:07:58', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'e35dfa67-5ed5-4eac-b7f2-eb3230f21222'	System	27 Aug 2020 23:08:02
User entered '27 Aug 2020 19:07'	System	27 Aug 2020 23:08:02

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:00:58
User entered 'Day 3'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-28T19:47:43', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'aeaddc6f-afe1-4c5c-a3f9-2ae5d3a6d041'	System	28 Aug 2020 23:48:17
User entered 'None (0)'	System	28 Aug 2020 23:48:17

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-28T19:47:47', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'aeaddc6f-afe1-4c5c-a3f9-2ae5d3a6d041'	System	28 Aug 2020 23:48:17
User entered 'None (0)'	System	28 Aug 2020 23:48:17

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-28T19:47:56', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'aeaddc6f-afe1-4c5c-a3f9-2ae5d3a6d041'	System	28 Aug 2020 23:48:17
User entered 'None (0)'	System	28 Aug 2020 23:48:17

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-28T19:48:00', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'aeaddc6f-afe1-4c5c-a3f9-2ae5d3a6d041'	System	28 Aug 2020 23:48:17
User entered 'None (0)'	System	28 Aug 2020 23:48:17

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-28T19:48:03', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'aeaddc6f-afe1-4c5c-a3f9-2ae5d3a6d041'	System	28 Aug 2020 23:48:17
User entered 'None (0)'	System	28 Aug 2020 23:48:17

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-28T19:48:07', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'aeaddc6f-afe1-4c5c-a3f9-2ae5d3a6d041'	System	28 Aug 2020 23:48:17
User entered 'None (0)'	System	28 Aug 2020 23:48:17

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-28T19:48:11', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'aeaddc6f-afe1-4c5c-a3f9-2ae5d3a6d041'	System	28 Aug 2020 23:48:17
User entered 'No (N)'	System	28 Aug 2020 23:48:17

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-28T19:48:15', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'aeaddc6f-afe1-4c5c-a3f9-2ae5d3a6d041'	System	28 Aug 2020 23:48:17
User entered '28 Aug 2020 19:48'	System	28 Aug 2020 23:48:17

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:00:58
User entered 'Day 4'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-29T22:07:44', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '09a51b20-ea2b-40c0-9d91-7daf6fc0f5d0'	System	30 Aug 2020 02:08:09
User entered 'None (0)'	System	30 Aug 2020 02:08:09

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-29T22:07:46', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '09a51b20-ea2b-40c0-9d91-7daf6fc0f5d0'	System	30 Aug 2020 02:08:09
User entered 'None (0)'	System	30 Aug 2020 02:08:09

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-29T22:07:49', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '09a51b20-ea2b-40c0-9d91-7daf6fc0f5d0'	System	30 Aug 2020 02:08:09
User entered 'None (0)'	System	30 Aug 2020 02:08:09

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-29T22:07:51', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '09a51b20-ea2b-40c0-9d91-7daf6fc0f5d0'	System	30 Aug 2020 02:08:09
User entered 'None (0)'	System	30 Aug 2020 02:08:09

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-29T22:07:54', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '09a51b20-ea2b-40c0-9d91-7daf6fc0f5d0'	System	30 Aug 2020 02:08:09
User entered 'None (0)'	System	30 Aug 2020 02:08:09

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-29T22:07:56', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '09a51b20-ea2b-40c0-9d91-7daf6fc0f5d0'	System	30 Aug 2020 02:08:09
User entered 'None (0)'	System	30 Aug 2020 02:08:09

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-29T22:08:02', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '09a51b20-ea2b-40c0-9d91-7daf6fc0f5d0'	System	30 Aug 2020 02:08:09
User entered 'No (N)'	System	30 Aug 2020 02:08:09

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-29T22:08:07', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '09a51b20-ea2b-40c0-9d91-7daf6fc0f5d0'	System	30 Aug 2020 02:08:09
User entered '29 Aug 2020 22:08'	System	30 Aug 2020 02:08:09

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:00:58
User entered 'Day 5'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-30T20:49:28', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '77e7a2f4-bf52-4901-8478-4e30237c4ed3'	System	31 Aug 2020 00:49:55
User entered 'None (0)'	System	31 Aug 2020 00:49:55

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-30T20:49:32', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '77e7a2f4-bf52-4901-8478-4e30237c4ed3'	System	31 Aug 2020 00:49:55
User entered 'None (0)'	System	31 Aug 2020 00:49:55

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-30T20:49:34', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '77e7a2f4-bf52-4901-8478-4e30237c4ed3'	System	31 Aug 2020 00:49:55
User entered 'None (0)'	System	31 Aug 2020 00:49:55

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-30T20:49:37', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '77e7a2f4-bf52-4901-8478-4e30237c4ed3'	System	31 Aug 2020 00:49:55
User entered 'None (0)'	System	31 Aug 2020 00:49:55

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-30T20:49:39', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '77e7a2f4-bf52-4901-8478-4e30237c4ed3'	System	31 Aug 2020 00:49:55
User entered 'None (0)'	System	31 Aug 2020 00:49:55

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-30T20:49:41', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '77e7a2f4-bf52-4901-8478-4e30237c4ed3'	System	31 Aug 2020 00:49:55
User entered 'None (0)'	System	31 Aug 2020 00:49:55

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-30T20:49:44', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '77e7a2f4-bf52-4901-8478-4e30237c4ed3'	System	31 Aug 2020 00:49:55
User entered 'No (N)'	System	31 Aug 2020 00:49:55

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-30T20:49:52', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '77e7a2f4-bf52-4901-8478-4e30237c4ed3'	System	31 Aug 2020 00:49:55
User entered '30 Aug 2020 20:49'	System	31 Aug 2020 00:49:55

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:00:58
User entered 'Day 6'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-31T21:22:42', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'b9a3f8b6-7e0e-4279-af48-cdce510e2150'	System	01 Sep 2020 01:23:08
User entered 'None (0)'	System	01 Sep 2020 01:23:08

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-31T21:22:44', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'b9a3f8b6-7e0e-4279-af48-cdce510e2150'	System	01 Sep 2020 01:23:08
User entered 'None (0)'	System	01 Sep 2020 01:23:08

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-31T21:22:46', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'b9a3f8b6-7e0e-4279-af48-cdce510e2150'	System	01 Sep 2020 01:23:08
User entered 'None (0)'	System	01 Sep 2020 01:23:08

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-31T21:22:50', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'b9a3f8b6-7e0e-4279-af48-cdce510e2150'	System	01 Sep 2020 01:23:08
User entered 'None (0)'	System	01 Sep 2020 01:23:08

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-31T21:22:53', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'b9a3f8b6-7e0e-4279-af48-cdce510e2150'	System	01 Sep 2020 01:23:08
User entered 'None (0)'	System	01 Sep 2020 01:23:08

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-31T21:22:56', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'b9a3f8b6-7e0e-4279-af48-cdce510e2150'	System	01 Sep 2020 01:23:08
User entered 'None (0)'	System	01 Sep 2020 01:23:08

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-31T21:22:59', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'b9a3f8b6-7e0e-4279-af48-cdce510e2150'	System	01 Sep 2020 01:23:08
User entered 'No (N)'	System	01 Sep 2020 01:23:08

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-08-31T21:23:05', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'b9a3f8b6-7e0e-4279-af48-cdce510e2150'	System	01 Sep 2020 01:23:08
User entered '31 Aug 2020 21:23'	System	01 Sep 2020 01:23:08

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:00:58
User entered 'Day 7'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-01T20:13:09', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '33b62b24-6e0c-4eab-885c-1054aab3baa5'	System	02 Sep 2020 00:13:33
User entered 'None (0)'	System	02 Sep 2020 00:13:33

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-01T20:13:11', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '33b62b24-6e0c-4eab-885c-1054aab3baa5'	System	02 Sep 2020 00:13:33
User entered 'None (0)'	System	02 Sep 2020 00:13:33

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-01T20:13:15', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '33b62b24-6e0c-4eab-885c-1054aab3baa5'	System	02 Sep 2020 00:13:33
User entered 'None (0)'	System	02 Sep 2020 00:13:33

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-01T20:13:18', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '33b62b24-6e0c-4eab-885c-1054aab3baa5'	System	02 Sep 2020 00:13:33
User entered 'None (0)'	System	02 Sep 2020 00:13:33

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-01T20:13:20', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '33b62b24-6e0c-4eab-885c-1054aab3baa5'	System	02 Sep 2020 00:13:33
User entered 'None (0)'	System	02 Sep 2020 00:13:33

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-01T20:13:23', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '33b62b24-6e0c-4eab-885c-1054aab3baa5'	System	02 Sep 2020 00:13:33
User entered 'None (0)'	System	02 Sep 2020 00:13:33

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-01T20:13:25', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '33b62b24-6e0c-4eab-885c-1054aab3baa5'	System	02 Sep 2020 00:13:33
User entered 'No (N)'	System	02 Sep 2020 00:13:33

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-01T20:13:30', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '33b62b24-6e0c-4eab-885c-1054aab3baa5'	System	02 Sep 2020 00:13:33
User entered '01 Sep 2020 20:13'	System	02 Sep 2020 00:13:33

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 20:00:58

US3802046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 20:00:58

US3802046

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4)	02 Sep 2020 16:27:33

US3802046

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered '2 Sep 2020'	(b) (4) Jennifer Nagg (b) (4)	02 Sep 2020 16:27:33
	(b) (4)	

US3802046

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jennifer Nagg (b) (4)	02 Sep 2020 16:27:33

US3802046

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	02 Sep 2020 16:27:33
	(b) (4)	

US3802046

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4)	02 Sep 2020 16:27:41

US3802046

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 16:27:41

US3802046

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'Yes (Y)'	Judith Martin (b) (4)	09 Sep 2020 18:08:09
	(b) (4)	

US3802046

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered '9 Sep 2020'	Judith Martin (b) (4)	09 Sep 2020 18:08:09
	(b) (4)	

US3802046

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'Contact Made (CONTACT MADE)'	Judith Martin (b) (4)	09 Sep 2020 18:08:09

US3802046

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered empty.	(b) (4) Judith Martin (b) (4)	09 Sep 2020 18:08:09
	(b) (4)	

US3802046

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4) (b) (4)	09 Sep 2020 18:08:40
User entered 'Yes (Y)'	Judith Martin (b) (4) (b) (4)	09 Sep 2020 18:08:16

US3802046

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 18:08:16

US3802046

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	18 Sep 2020 13:57:44
	(b) (4)	
User entered 'Yes (Y)'	Judith Martin (b) (4)	18 Sep 2020 13:57:22
	(b) (4)	

US3802046

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	18 Sep 2020 13:57:44
	(b) (4)	
User entered '17 Sep 2020'	Judith Martin (b) (4)	18 Sep 2020 13:57:22
	(b) (4)	

US3802046

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	18 Sep 2020 13:57:44
User entered 'Contact Made (CONTACT MADE)'	Judith Martin (b) (4)	18 Sep 2020 13:57:22

US3802046

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4) (b) (4)	18 Sep 2020 13:57:44
User entered empty.	Judith Martin (b) (4) (b) (4)	18 Sep 2020 13:57:22

US3802046

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4) (b) (4)	18 Sep 2020 13:57:44
User entered 'Yes (Y)'	Judith Martin (b) (4) (b) (4)	18 Sep 2020 13:57:29

US3802046

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 13:57:29

US3802046

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4)	23 Sep 2020 13:25:13

US3802046

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
User entered '23 Sep 2020'	(b) (4) Jennifer Nagg (b) (4)	23 Sep 2020 13:25:13

US3802046

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
User entered 'Clinic (Clinic)'	(b) (4) Jennifer Nagg (b) (4)	23 Sep 2020 13:25:13

US3802046

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	23 Sep 2020 13:25:13

US3802046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Dominic Kramer (b) (4) (b) (4)	23 Sep 2020 14:02:05

US3802046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
	(b) (4)	
User entered 'Yes (Y)'	Dominic Kramer (b) (4)	23 Sep 2020 14:02:05
	(b) (4)	

US3802046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
	(b) (4)	
User entered '23 Sep 2020'	Dominic Kramer (b) (4)	23 Sep 2020 14:02:05
	(b) (4)	

US3802046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4) (b) (4)	08 Oct 2020 19:06:29
User entered '9:10'	Dominic Kramer (b) (4) (b) (4)	23 Sep 2020 14:02:05

US3802046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '23 Sep 2020 9:10'	System	23 Sep 2020 14:02:05

US3802046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
	(b) (4)	
User entered '97.2' F	Dominic Kramer (b) (4)	23 Sep 2020 14:02:05
	(b) (4)	

US3802046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
	(b) (4)	
User entered 'Other (Other)'	Dominic Kramer (b) (4)	23 Sep 2020 14:02:05
	(b) (4)	

US3802046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
	(b) (4)	
User entered 'Infrared'	Dominic Kramer (b) (4)	23 Sep 2020 14:02:05
	(b) (4)	

US3802046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
	(b) (4)	
User entered '67'	Dominic Kramer (b) (4)	23 Sep 2020 14:02:05
	(b) (4)	

US3802046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	23 Sep 2020 14:02:05

US3802046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
	(b) (4)	
User entered '18'	Dominic Kramer (b) (4)	23 Sep 2020 14:02:05
	(b) (4)	

US3802046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	23 Sep 2020 14:02:05

US3802046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
	(b) (4)	
User entered '150'	Dominic Kramer (b) (4)	23 Sep 2020 14:02:05
	(b) (4)	

US3802046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Sep 2020 14:02:05

US3802046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
	(b) (4)	
User entered '86'	Dominic Kramer (b) (4)	23 Sep 2020 14:02:05
	(b) (4)	

US3802046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Sep 2020 14:02:05

US3802046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Dominic Kramer (b) (4) (b) (4)	23 Sep 2020 14:02:05

US3802046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
	(b) (4)	
User entered 'Yes (Y)'	Dominic Kramer (b) (4)	23 Sep 2020 14:02:05
	(b) (4)	

US3802046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
	(b) (4)	
User entered '23 Sep 2020'	Dominic Kramer (b) (4)	23 Sep 2020 14:02:05
	(b) (4)	

US3802046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
	(b) (4)	
User entered '9:51'	Dominic Kramer (b) (4)	23 Sep 2020 14:02:05
	(b) (4)	

US3802046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '23 Sep 2020 9:51'	System	23 Sep 2020 14:02:05

US3802046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM: Site response noted; however, please confirm if CS or NCS and report AE if appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 08:35:15
User signature succeeded.	Judith Martin (b) (4) (b) (4)	08 Oct 2020 19:06:29
Query 'Per CDM: Site response noted; however, please confirm if CS or NCS and report AE if appropriate. Thank you. ' answered with 'NCS' (Site from DM).	Melissa Andrasko (b) (4)	06 Oct 2020 14:56:00
User opened query 'Per CDM: Site response noted; however, please confirm if CS or NCS and report AE if appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 08:43:13
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)	28 Sep 2020 08:43:09
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.' answered with 'Actual Value ' (Site from System).	Dominic Kramer (b) (4) (b) (4)	23 Sep 2020 14:02:23
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	23 Sep 2020 14:02:05
User entered '96.7' F	Dominic Kramer (b) (4) (b) (4)	23 Sep 2020 14:02:05

US3802046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
	(b) (4)	
User entered 'Other (Other)'	Dominic Kramer (b) (4)	23 Sep 2020 14:02:05
	(b) (4)	

US3802046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
	(b) (4)	
User entered 'Infrared'	Dominic Kramer (b) (4)	23 Sep 2020 14:02:05
	(b) (4)	

US3802046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
	(b) (4)	
User entered '61'	Dominic Kramer (b) (4)	23 Sep 2020 14:02:05
	(b) (4)	

US3802046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	23 Sep 2020 14:02:05

US3802046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
	(b) (4)	
User entered '18'	Dominic Kramer (b) (4)	23 Sep 2020 14:02:05
	(b) (4)	

US3802046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	23 Sep 2020 14:02:05

US3802046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
	(b) (4)	
User entered '128'	Dominic Kramer (b) (4)	23 Sep 2020 14:02:05
	(b) (4)	

US3802046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Sep 2020 14:02:05

US3802046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
	(b) (4)	
User entered '70'	Dominic Kramer (b) (4)	23 Sep 2020 14:02:05
	(b) (4)	

US3802046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Sep 2020 14:02:05

US3802046

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
User entered 'No (N)'	(b) (4) Jennifer Nagg (b) (4)	23 Sep 2020 13:25:18

US3802046

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
	(b) (4)	
User entered empty.	Jennifer Nagg (b) (4)	23 Sep 2020 13:25:18
	(b) (4)	

US3802046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
	(b) (4)	
User entered 'Yes (Y)'	Jennifer Nagg (b) (4)	23 Sep 2020 13:25:38
	(b) (4)	

US3802046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
	(b) (4)	
User entered empty.	Jennifer Nagg (b) (4)	23 Sep 2020 13:25:38
	(b) (4)	

US3802046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	23 Sep 2020 13:25:38
	(b) (4)	

US3802046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	23 Sep 2020 13:25:38

US3802046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
User entered '23 Sep 2020'	(b) (4) Jennifer Nagg (b) (4)	23 Sep 2020 13:25:38

US3802046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
User entered '09:18'	(b) (4) Jennifer Nagg (b) (4)	23 Sep 2020 13:25:38

US3802046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '23 Sep 2020 09:18'	System	23 Sep 2020 13:25:38

US3802046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
User entered 'Left Arm (LEFT ARM)'	(b) (4) Jennifer Nagg (b) (4)	23 Sep 2020 13:25:38

US3802046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	23 Sep 2020 13:25:38

US3802046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	23 Sep 2020 13:25:38

US3802046

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4)	23 Sep 2020 13:26:40

US3802046

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
	(b) (4)	
User entered '23 Sep 2020'	Jennifer Nagg (b) (4)	23 Sep 2020 13:26:40
	(b) (4)	

US3802046

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
	(b) (4)	
User entered '09:10'	Jennifer Nagg (b) (4)	23 Sep 2020 13:26:40
	(b) (4)	

US3802046

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '23 Sep 2020 09:10'	System	23 Sep 2020 13:26:40

US3802046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:20:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
User entered '23 Sep 2020'	(b) (4) Jennifer Nagg (b) (4)	23 Sep 2020 13:27:05

US3802046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:20:44

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jennifer Nagg (b) (4)	23 Sep 2020 13:27:05

US3802046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:20:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4)	23 Sep 2020 13:27:05

US3802046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:20:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
User entered '09:05'	(b) (4) Jennifer Nagg (b) (4)	23 Sep 2020 13:27:05
	(b) (4)	

US3802046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '23 Sep 2020 09:05'	System	23 Sep 2020 13:27:05

US3802046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:20:44

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jennifer Nagg (b) (4)	23 Sep 2020 13:27:05

US3802046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:20:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
User entered 'No (N)'	(b) (4) Jennifer Nagg (b) (4)	23 Sep 2020 13:27:05

US3802046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
	(b) (4)	
User entered empty.	Jennifer Nagg (b) (4)	23 Sep 2020 13:27:05
	(b) (4)	

US3802046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 13:27:05

US3802046

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
	(b) (4)	
User entered 'Yes (Y)'	Jennifer Nagg (b) (4)	23 Sep 2020 13:27:11
	(b) (4)	

US3802046

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 13:27:11

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 13:25:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-23T10:06:27', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '03fc9241-3763-43b0-ae7c-d7f6eacb6054'	System	23 Sep 2020 14:06:56
User entered 'Yes (Y)'	System	23 Sep 2020 14:06:56

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-23T10:06:39', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '03fc9241-3763-43b0-ae7c-d7f6eacb6054'	System	23 Sep 2020 14:06:56
User entered '96.7'	System	23 Sep 2020 14:06:56

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-23T10:06:43', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '03fc9241-3763-43b0-ae7c-d7f6eacb6054'	System	23 Sep 2020 14:06:56
User entered 'No (N)'	System	23 Sep 2020 14:06:56

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-23T10:06:52', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '03fc9241-3763-43b0-ae7c-d7f6eacb6054'	System	23 Sep 2020 14:06:56
User entered '23 Sep 2020 10:06'	System	23 Sep 2020 14:06:56

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 09:38'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:08'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 13:25:38
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-23T19:05:25', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '540d9b36-e10d-4e36-acdf-7c538304efe0'	System	23 Sep 2020 23:06:35
User entered 'Yes (Y)'	System	23 Sep 2020 23:06:35

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-23T19:06:16', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '540d9b36-e10d-4e36-acdf-7c538304efe0' User entered '98.2'	System	23 Sep 2020 23:06:35
	System	23 Sep 2020 23:06:35

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-23T19:06:24', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '540d9b36-e10d-4e36-acdf-7c538304efe0'	System	23 Sep 2020 23:06:35
User entered 'No (N)'	System	23 Sep 2020 23:06:35

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-23T19:06:29', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '540d9b36-e10d-4e36-acdf-7c538304efe0'	System	23 Sep 2020 23:06:35
User entered '23 Sep 2020 19:06'	System	23 Sep 2020 23:06:35

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 13:03'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 13:25:38
User entered 'Day 2'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-24T18:49:35', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '1769be6e-e6f0-478f-8661-f481b5980462'	System	24 Sep 2020 22:49:58
User entered 'Yes (Y)'	System	24 Sep 2020 22:49:58

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-24T18:49:44', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '1769be6e-e6f0-478f-8661-f481b5980462' User entered '96.1'	System	24 Sep 2020 22:49:58
	System	24 Sep 2020 22:49:58

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-24T18:49:49', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '1769be6e-e6f0-478f-8661-f481b5980462'	System	24 Sep 2020 22:49:58
User entered 'No (N)'	System	24 Sep 2020 22:49:58

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-24T18:49:55', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '1769be6e-e6f0-478f-8661-f481b5980462'	System	24 Sep 2020 22:49:58
User entered '24 Sep 2020 18:49'	System	24 Sep 2020 22:49:58

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 13:25:38
User entered 'Day 3'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-25T20:19:37', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '05b8bb26-53ab-4706-bb7f-2c3aead12caf'	System	26 Sep 2020 00:20:44
User entered 'Yes (Y)'	System	26 Sep 2020 00:20:44

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-25T20:20:30', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '05b8bb26-53ab-4706-bb7f-2c3aead12caf'	System	26 Sep 2020 00:20:44
User entered '97.9'	System	26 Sep 2020 00:20:44

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-25T20:20:38', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '05b8bb26-53ab-4706-bb7f-2c3aead12caf'	System	26 Sep 2020 00:20:44
User entered 'No (N)'	System	26 Sep 2020 00:20:44

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-25T20:20:43', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '05b8bb26-53ab-4706-bb7f-2c3aead12caf'	System	26 Sep 2020 00:20:44
User entered '25 Sep 2020 20:20'	System	26 Sep 2020 00:20:44

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 13:25:38
User entered 'Day 4'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-26T19:26:30', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '305f35bd-e435-4b44-9dbc-f56d6bf04de8'	System	26 Sep 2020 23:27:01
User entered 'Yes (Y)'	System	26 Sep 2020 23:27:01

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-26T19:26:42', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '305f35bd-e435-4b44-9dbc-f56d6bf04de8' User entered '97.9'	System	26 Sep 2020 23:27:01
	System	26 Sep 2020 23:27:01

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-26T19:26:47', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '305f35bd-e435-4b44-9dbc-f56d6bf04de8'	System	26 Sep 2020 23:27:01
User entered 'No (N)'	System	26 Sep 2020 23:27:01

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-26T19:26:55', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '305f35bd-e435-4b44-9dbc-f56d6bf04de8' User entered '26 Sep 2020 19:26'	System	26 Sep 2020 23:27:01
	System	26 Sep 2020 23:27:01

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 13:25:38
User entered 'Day 5'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-27T20:32:53', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '49e2355c-7614-4248-900c-1f643971d0f2'	System	28 Sep 2020 00:34:08
User entered 'Yes (Y)'	System	28 Sep 2020 00:34:08

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-27T20:33:54', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '49e2355c-7614-4248-900c-1f643971d0f2'	System	28 Sep 2020 00:34:08
User entered '97.4'	System	28 Sep 2020 00:34:08

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-27T20:34:00', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '49e2355c-7614-4248-900c-1f643971d0f2'	System	28 Sep 2020 00:34:08
User entered 'No (N)'	System	28 Sep 2020 00:34:08

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-27T20:34:04', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '49e2355c-7614-4248-900c-1f643971d0f2'	System	28 Sep 2020 00:34:08
User entered '27 Sep 2020 20:34'	System	28 Sep 2020 00:34:08

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 13:25:38
User entered 'Day 6'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-28T20:51:47', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'd4f6adb1-bb5e-490a-8557-1a4956e78f65'	System	29 Sep 2020 00:54:37
User entered 'Yes (Y)'	System	29 Sep 2020 00:54:37

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-28T20:54:22', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'd4f6adb1-bb5e-490a-8557-1a4956e78f65'	System	29 Sep 2020 00:54:37
User entered '97.2'	System	29 Sep 2020 00:54:37

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-28T20:54:26', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'd4f6adb1-bb5e-490a-8557-1a4956e78f65'	System	29 Sep 2020 00:54:37
User entered 'No (N)'	System	29 Sep 2020 00:54:37

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-28T20:54:31', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'd4f6adb1-bb5e-490a-8557-1a4956e78f65'	System	29 Sep 2020 00:54:37
User entered '28 Sep 2020 20:54'	System	29 Sep 2020 00:54:37

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 13:25:38
User entered 'Day 7'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-29T19:51:53', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'fed7df68-fe89-4a56-9dee-2e65a09ad801'	System	29 Sep 2020 23:53:21
User entered 'Yes (Y)'	System	29 Sep 2020 23:53:21

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-29T19:53:12', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'fed7df68-fe89-4a56-9dee-2e65a09ad801'	System	29 Sep 2020 23:53:21
User entered '97.0'	System	29 Sep 2020 23:53:21

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-29T19:53:16', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'fed7df68-fe89-4a56-9dee-2e65a09ad801'	System	29 Sep 2020 23:53:21
User entered 'No (N)'	System	29 Sep 2020 23:53:21

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-29T19:53:19', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'fed7df68-fe89-4a56-9dee-2e65a09ad801'	System	29 Sep 2020 23:53:21
User entered '29 Sep 2020 19:53'	System	29 Sep 2020 23:53:21

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 13:25:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-23T10:07:01', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '01c30231-0c71-48bf-a4cf-3aee46b70727'	System	23 Sep 2020 14:07:20
User entered 'None (1)'	System	23 Sep 2020 14:07:20

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-23T10:07:04', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '01c30231-0c71-48bf-a4cf-3aee46b70727'	System	23 Sep 2020 14:07:20
User entered 'No (N)'	System	23 Sep 2020 14:07:20

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-23T10:07:07', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '01c30231-0c71-48bf-a4cf-3aee46b70727'	System	23 Sep 2020 14:07:20
User entered 'No (N)'	System	23 Sep 2020 14:07:20

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-23T10:07:12', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '01c30231-0c71-48bf-a4cf-3aee46b70727'	System	23 Sep 2020 14:07:20
User entered 'None (1)'	System	23 Sep 2020 14:07:20

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-23T10:07:18', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '01c30231-0c71-48bf-a4cf-3aee46b70727'	System	23 Sep 2020 14:07:20
User entered '23 Sep 2020 10:07'	System	23 Sep 2020 14:07:20

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 09:38'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:08'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 13:25:38
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-23T19:06:45', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '97e0577a-189b-4b0c-84b8-e0b719f46d5f'	System	23 Sep 2020 23:07:28
User entered 'None (1)'	System	23 Sep 2020 23:07:28

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-23T19:07:03', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '97e0577a-189b-4b0c-84b8-e0b719f46d5f' User entered 'No (N)'	System	23 Sep 2020 23:07:28
	System	23 Sep 2020 23:07:28

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-23T19:07:08', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '97e0577a-189b-4b0c-84b8-e0b719f46d5f' User entered 'No (N)'	System	23 Sep 2020 23:07:28
	System	23 Sep 2020 23:07:28

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-23T19:07:20', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '97e0577a-189b-4b0c-84b8-e0b719f46d5f' User entered 'None (1)'	System	23 Sep 2020 23:07:28
	System	23 Sep 2020 23:07:28

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-23T19:07:26', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '97e0577a-189b-4b0c-84b8-e0b719f46d5f' User entered '23 Sep 2020 19:07'	System	23 Sep 2020 23:07:28
	System	23 Sep 2020 23:07:28

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 13:03'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 13:25:38
User entered 'Day 2'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-24T18:50:09', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'a5c82f4a-5fec-46bf-86ee-4116d4ceb685'	System	24 Sep 2020 22:50:37
User entered 'None (1)'	System	24 Sep 2020 22:50:37

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-24T18:50:15', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'a5c82f4a-5fec-46bf-86ee-4116d4ceb685'	System	24 Sep 2020 22:50:37
User entered 'No (N)'	System	24 Sep 2020 22:50:37

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-24T18:50:18', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'a5c82f4a-5fec-46bf-86ee-4116d4ceb685'	System	24 Sep 2020 22:50:37
User entered 'No (N)'	System	24 Sep 2020 22:50:37

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-24T18:50:27', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'a5c82f4a-5fec-46bf-86ee-4116d4ceb685'	System	24 Sep 2020 22:50:37
User entered 'None (1)'	System	24 Sep 2020 22:50:37

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-24T18:50:36', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'a5c82f4a-5fec-46bf-86ee-4116d4ceb685'	System	24 Sep 2020 22:50:37
User entered '24 Sep 2020 18:50'	System	24 Sep 2020 22:50:37

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 13:25:38
User entered 'Day 3'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-25T20:20:49', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '77a91bb4-8e86-4dad-828e-1ce5877afd12'	System	26 Sep 2020 00:21:02
User entered 'None (1)'	System	26 Sep 2020 00:21:02

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-25T20:20:52', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '77a91bb4-8e86-4dad-828e-1ce5877afd12'	System	26 Sep 2020 00:21:02
User entered 'No (N)'	System	26 Sep 2020 00:21:02

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-25T20:20:54', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '77a91bb4-8e86-4dad-828e-1ce5877afd12'	System	26 Sep 2020 00:21:02
User entered 'No (N)'	System	26 Sep 2020 00:21:02

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-25T20:20:57', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '77a91bb4-8e86-4dad-828e-1ce5877afd12'	System	26 Sep 2020 00:21:02
User entered 'None (1)'	System	26 Sep 2020 00:21:02

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-25T20:21:01', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '77a91bb4-8e86-4dad-828e-1ce5877afd12'	System	26 Sep 2020 00:21:02
User entered '25 Sep 2020 20:21'	System	26 Sep 2020 00:21:02

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 13:25:38
User entered 'Day 4'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-26T19:27:02', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '76517ec2-53b0-4f1e-94ca-5104e571a784'	System	26 Sep 2020 23:27:25
User entered 'None (1)'	System	26 Sep 2020 23:27:25

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-26T19:27:06', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '76517ec2-53b0-4f1e-94ca-5104e571a784'	System	26 Sep 2020 23:27:25
User entered 'No (N)'	System	26 Sep 2020 23:27:25

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-26T19:27:09', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '76517ec2-53b0-4f1e-94ca-5104e571a784'	System	26 Sep 2020 23:27:25
User entered 'No (N)'	System	26 Sep 2020 23:27:25

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-26T19:27:16', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '76517ec2-53b0-4f1e-94ca-5104e571a784'	System	26 Sep 2020 23:27:25
User entered 'None (1)'	System	26 Sep 2020 23:27:25

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-26T19:27:23', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '76517ec2-53b0-4f1e-94ca-5104e571a784'	System	26 Sep 2020 23:27:25
User entered '26 Sep 2020 19:27'	System	26 Sep 2020 23:27:25

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 13:25:38
User entered 'Day 5'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-27T20:34:11', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '584bc1ae-7d36-4302-b689-2d9f2fcd64f5'	System	28 Sep 2020 00:34:37
User entered 'None (1)'	System	28 Sep 2020 00:34:37

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-27T20:34:17', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '584bc1ae-7d36-4302-b689-2d9f2fcd64f5'	System	28 Sep 2020 00:34:37
User entered 'No (N)'	System	28 Sep 2020 00:34:37

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-27T20:34:23', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '584bc1ae-7d36-4302-b689-2d9f2fcd64f5'	System	28 Sep 2020 00:34:37
User entered 'No (N)'	System	28 Sep 2020 00:34:37

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-27T20:34:29', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '584bc1ae-7d36-4302-b689-2d9f2fcd64f5'	System	28 Sep 2020 00:34:37
User entered 'None (1)'	System	28 Sep 2020 00:34:37

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-27T20:34:34', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '584bc1ae-7d36-4302-b689-2d9f2fcd64f5'	System	28 Sep 2020 00:34:37
User entered '27 Sep 2020 20:34'	System	28 Sep 2020 00:34:37

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 13:25:38
User entered 'Day 6'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-28T20:54:38', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '63fa018f-7596-44f7-9622-01befd0d9b5d'	System	29 Sep 2020 00:54:53
User entered 'None (1)'	System	29 Sep 2020 00:54:53

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-28T20:54:41', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '63fa018f-7596-44f7-9622-01befd0d9b5d'	System	29 Sep 2020 00:54:53
User entered 'No (N)'	System	29 Sep 2020 00:54:53

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-28T20:54:45', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '63fa018f-7596-44f7-9622-01befd0d9b5d'	System	29 Sep 2020 00:54:53
User entered 'No (N)'	System	29 Sep 2020 00:54:53

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-28T20:54:48', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '63fa018f-7596-44f7-9622-01befd0d9b5d'	System	29 Sep 2020 00:54:53
User entered 'None (1)'	System	29 Sep 2020 00:54:53

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-28T20:54:51', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '63fa018f-7596-44f7-9622-01befd0d9b5d'	System	29 Sep 2020 00:54:53
User entered '28 Sep 2020 20:54'	System	29 Sep 2020 00:54:53

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 13:25:38
User entered 'Day 7'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-29T19:53:24', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '09b6ca66-c888-4713-8d31-7f1df77750c1'	System	29 Sep 2020 23:53:38
User entered 'None (1)'	System	29 Sep 2020 23:53:38

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-29T19:53:28', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '09b6ca66-c888-4713-8d31-7f1df77750c1'	System	29 Sep 2020 23:53:38
User entered 'No (N)'	System	29 Sep 2020 23:53:38

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-29T19:53:31', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '09b6ca66-c888-4713-8d31-7f1df77750c1'	System	29 Sep 2020 23:53:38
User entered 'No (N)'	System	29 Sep 2020 23:53:38

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-29T19:53:33', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '09b6ca66-c888-4713-8d31-7f1df77750c1'	System	29 Sep 2020 23:53:38
User entered 'None (1)'	System	29 Sep 2020 23:53:38

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-29T19:53:36', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '09b6ca66-c888-4713-8d31-7f1df77750c1' User entered '29 Sep 2020 19:53'	System	29 Sep 2020 23:53:38
	System	29 Sep 2020 23:53:38

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 13:25:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-23T10:07:24', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '33986729-29d1-467a-9bb4-f88f13f491f3'	System	23 Sep 2020 14:07:50
User entered 'None (0)'	System	23 Sep 2020 14:07:50

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-23T10:07:27', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '33986729-29d1-467a-9bb4-f88f13f491f3'	System	23 Sep 2020 14:07:50
User entered 'None (0)'	System	23 Sep 2020 14:07:50

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-23T10:07:30', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '33986729-29d1-467a-9bb4-f88f13f491f3'	System	23 Sep 2020 14:07:50
User entered 'None (0)'	System	23 Sep 2020 14:07:50

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-23T10:07:33', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '33986729-29d1-467a-9bb4-f88f13f491f3'	System	23 Sep 2020 14:07:50
User entered 'None (0)'	System	23 Sep 2020 14:07:50

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-23T10:07:35', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '33986729-29d1-467a-9bb4-f88f13f491f3'	System	23 Sep 2020 14:07:50
User entered 'None (0)'	System	23 Sep 2020 14:07:50

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-23T10:07:38', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '33986729-29d1-467a-9bb4-f88f13f491f3'	System	23 Sep 2020 14:07:50
User entered 'None (0)'	System	23 Sep 2020 14:07:50

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-23T10:07:42', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '33986729-29d1-467a-9bb4-f88f13f491f3'	System	23 Sep 2020 14:07:50
User entered 'No (N)'	System	23 Sep 2020 14:07:50

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-23T10:07:45', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '33986729-29d1-467a-9bb4-f88f13f491f3'	System	23 Sep 2020 14:07:50
User entered '23 Sep 2020 10:07'	System	23 Sep 2020 14:07:50

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 09:38'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:08'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 13:25:38
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-23T19:07:42', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '75ff122d-d9fc-4e2e-90a8-d1e732807b2a'	System	23 Sep 2020 23:10:22
User entered 'No interference with activity (1)'	System	23 Sep 2020 23:10:22

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-23T19:07:50', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '75ff122d-d9fc-4e2e-90a8-d1e732807b2a'	System	23 Sep 2020 23:10:22
User entered 'None (0)'	System	23 Sep 2020 23:10:22

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-23T19:07:56', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '75ff122d-d9fc-4e2e-90a8-d1e732807b2a'	System	23 Sep 2020 23:10:22
User entered 'None (0)'	System	23 Sep 2020 23:10:22

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-23T19:07:59', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '75ff122d-d9fc-4e2e-90a8-d1e732807b2a'	System	23 Sep 2020 23:10:22
User entered 'None (0)'	System	23 Sep 2020 23:10:22

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-23T19:08:06', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '75ff122d-d9fc-4e2e-90a8-d1e732807b2a'	System	23 Sep 2020 23:10:22
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	23 Sep 2020 23:10:22

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-23T19:10:12', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '75ff122d-d9fc-4e2e-90a8-d1e732807b2a'	System	23 Sep 2020 23:10:22
User entered 'None (0)'	System	23 Sep 2020 23:10:22

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-23T19:10:16', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '75ff122d-d9fc-4e2e-90a8-d1e732807b2a'	System	23 Sep 2020 23:10:22
User entered 'No (N)'	System	23 Sep 2020 23:10:22

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-23T19:10:20', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '75ff122d-d9fc-4e2e-90a8-d1e732807b2a'	System	23 Sep 2020 23:10:22
User entered '23 Sep 2020 19:10'	System	23 Sep 2020 23:10:22

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 13:03'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 13:25:38
User entered 'Day 2'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-24T18:50:46', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'f6ca0915-3036-4a8a-a128-762860440906'	System	24 Sep 2020 22:51:27
User entered 'No interference with activity (1)'	System	24 Sep 2020 22:51:27

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-24T18:50:57', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'f6ca0915-3036-4a8a-a128-762860440906'	System	24 Sep 2020 22:51:27
User entered 'No interference with activity (1)'	System	24 Sep 2020 22:51:27

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-24T18:51:05', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'f6ca0915-3036-4a8a-a128-762860440906' User entered 'None (0)'	System	24 Sep 2020 22:51:27
	System	24 Sep 2020 22:51:27

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-24T18:51:10', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'f6ca0915-3036-4a8a-a128-762860440906' User entered 'None (0)'	System	24 Sep 2020 22:51:27
	System	24 Sep 2020 22:51:27

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-24T18:51:15', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'f6ca0915-3036-4a8a-a128-762860440906' User entered 'None (0)'	System	24 Sep 2020 22:51:27
	System	24 Sep 2020 22:51:27

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-24T18:51:19', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'f6ca0915-3036-4a8a-a128-762860440906' User entered 'None (0)'	System	24 Sep 2020 22:51:27
	System	24 Sep 2020 22:51:27

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-24T18:51:22', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'f6ca0915-3036-4a8a-a128-762860440906'	System	24 Sep 2020 22:51:27
User entered 'No (N)'	System	24 Sep 2020 22:51:27

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-24T18:51:26', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'f6ca0915-3036-4a8a-a128-762860440906'	System	24 Sep 2020 22:51:27
User entered '24 Sep 2020 18:51'	System	24 Sep 2020 22:51:27

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 13:25:38
User entered 'Day 3'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-25T20:21:09', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '480c3a99-1ad3-4c5b-bdb1-47715035b777'	System	26 Sep 2020 00:21:45
User entered 'None (0)'	System	26 Sep 2020 00:21:45

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-25T20:21:14', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '480c3a99-1ad3-4c5b-bdb1-47715035b777'	System	26 Sep 2020 00:21:45
User entered 'None (0)'	System	26 Sep 2020 00:21:45

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-25T20:21:19', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '480c3a99-1ad3-4c5b-bdb1-47715035b777'	System	26 Sep 2020 00:21:45
User entered 'None (0)'	System	26 Sep 2020 00:21:45

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-25T20:21:22', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '480c3a99-1ad3-4c5b-bdb1-47715035b777'	System	26 Sep 2020 00:21:45
User entered 'None (0)'	System	26 Sep 2020 00:21:45

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-25T20:21:33', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '480c3a99-1ad3-4c5b-bdb1-47715035b777'	System	26 Sep 2020 00:21:45
User entered 'None (0)'	System	26 Sep 2020 00:21:45

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-25T20:21:36', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '480c3a99-1ad3-4c5b-bdb1-47715035b777'	System	26 Sep 2020 00:21:45
User entered 'None (0)'	System	26 Sep 2020 00:21:45

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-25T20:21:39', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '480c3a99-1ad3-4c5b-bdb1-47715035b777'	System	26 Sep 2020 00:21:45
User entered 'No (N)'	System	26 Sep 2020 00:21:45

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-25T20:21:43', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '480c3a99-1ad3-4c5b-bdb1-47715035b777'	System	26 Sep 2020 00:21:45
User entered '25 Sep 2020 20:21'	System	26 Sep 2020 00:21:45

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 13:25:38
User entered 'Day 4'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-26T19:27:46', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '8fa46df5-8e58-4c55-b8c4-d6233e6af965'	System	26 Sep 2020 23:28:19
User entered 'None (0)'	System	26 Sep 2020 23:28:19

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-26T19:27:54', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '8fa46df5-8e58-4c55-b8c4-d6233e6af965'	System	26 Sep 2020 23:28:19
User entered 'None (0)'	System	26 Sep 2020 23:28:19

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-26T19:27:57', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '8fa46df5-8e58-4c55-b8c4-d6233e6af965'	System	26 Sep 2020 23:28:19
User entered 'None (0)'	System	26 Sep 2020 23:28:19

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-26T19:28:01', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '8fa46df5-8e58-4c55-b8c4-d6233e6af965'	System	26 Sep 2020 23:28:19
User entered 'None (0)'	System	26 Sep 2020 23:28:19

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-26T19:28:04', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '8fa46df5-8e58-4c55-b8c4-d6233e6af965'	System	26 Sep 2020 23:28:19
User entered 'None (0)'	System	26 Sep 2020 23:28:19

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-26T19:28:07', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '8fa46df5-8e58-4c55-b8c4-d6233e6af965'	System	26 Sep 2020 23:28:19
User entered 'None (0)'	System	26 Sep 2020 23:28:19

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-26T19:28:10', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '8fa46df5-8e58-4c55-b8c4-d6233e6af965'	System	26 Sep 2020 23:28:19
User entered 'No (N)'	System	26 Sep 2020 23:28:19

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-26T19:28:15', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '8fa46df5-8e58-4c55-b8c4-d6233e6af965'	System	26 Sep 2020 23:28:19
User entered '26 Sep 2020 19:28'	System	26 Sep 2020 23:28:19

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 13:25:38
User entered 'Day 5'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-27T20:34:41', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'c92d2f1e-ced6-4a82-bdc6-94c0ba03d178'	System	28 Sep 2020 00:35:08
User entered 'None (0)'	System	28 Sep 2020 00:35:08

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-27T20:34:43', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'c92d2f1e-ced6-4a82-bdc6-94c0ba03d178'	System	28 Sep 2020 00:35:08
User entered 'None (0)'	System	28 Sep 2020 00:35:08

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-27T20:34:45', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'c92d2f1e-ced6-4a82-bdc6-94c0ba03d178'	System	28 Sep 2020 00:35:08
User entered 'None (0)'	System	28 Sep 2020 00:35:08

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-27T20:34:49', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'c92d2f1e-ced6-4a82-bdc6-94c0ba03d178'	System	28 Sep 2020 00:35:08
User entered 'None (0)'	System	28 Sep 2020 00:35:08

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-27T20:34:53', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'c92d2f1e-ced6-4a82-bdc6-94c0ba03d178'	System	28 Sep 2020 00:35:08
User entered 'None (0)'	System	28 Sep 2020 00:35:08

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-27T20:34:56', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'c92d2f1e-ced6-4a82-bdc6-94c0ba03d178'	System	28 Sep 2020 00:35:08
User entered 'None (0)'	System	28 Sep 2020 00:35:08

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-27T20:35:00', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'c92d2f1e-ced6-4a82-bdc6-94c0ba03d178'	System	28 Sep 2020 00:35:08
User entered 'No (N)'	System	28 Sep 2020 00:35:08

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-27T20:35:03', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'c92d2f1e-ced6-4a82-bdc6-94c0ba03d178'	System	28 Sep 2020 00:35:08
User entered '27 Sep 2020 20:35'	System	28 Sep 2020 00:35:08

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 13:25:38
User entered 'Day 6'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-28T20:55:00', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '77b1057a-00ab-4bb2-b916-45040535251e' User entered 'None (0)'	System	29 Sep 2020 00:55:28
	System	29 Sep 2020 00:55:28

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-28T20:55:04', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '77b1057a-00ab-4bb2-b916-45040535251e' User entered 'None (0)'	System	29 Sep 2020 00:55:28
	System	29 Sep 2020 00:55:28

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-28T20:55:06', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '77b1057a-00ab-4bb2-b916-45040535251e' User entered 'None (0)'	System	29 Sep 2020 00:55:28
	System	29 Sep 2020 00:55:28

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-28T20:55:12', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '77b1057a-00ab-4bb2-b916-45040535251e' User entered 'None (0)'	System	29 Sep 2020 00:55:28

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-28T20:55:16', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '77b1057a-00ab-4bb2-b916-45040535251e'	System	29 Sep 2020 00:55:28
User entered 'None (0)'	System	29 Sep 2020 00:55:28

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-28T20:55:19', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '77b1057a-00ab-4bb2-b916-45040535251e' User entered 'None (0)'	System	29 Sep 2020 00:55:28
	System	29 Sep 2020 00:55:28

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-28T20:55:23', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '77b1057a-00ab-4bb2-b916-45040535251e'	System	29 Sep 2020 00:55:28
User entered 'No (N)'	System	29 Sep 2020 00:55:28

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-28T20:55:25', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '77b1057a-00ab-4bb2-b916-45040535251e' User entered '28 Sep 2020 20:55'	System	29 Sep 2020 00:55:28
	System	29 Sep 2020 00:55:28

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 13:25:38
User entered 'Day 7'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-29T19:53:40', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '7b76f80a-f052-4663-8a3d-00ae5245ee2a' User entered 'None (0)'	System	29 Sep 2020 23:54:04
	System	29 Sep 2020 23:54:04

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-29T19:53:42', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '7b76f80a-f052-4663-8a3d-00ae5245ee2a'	System	29 Sep 2020 23:54:04
User entered 'None (0)'	System	29 Sep 2020 23:54:04

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-29T19:53:45', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '7b76f80a-f052-4663-8a3d-00ae5245ee2a'	System	29 Sep 2020 23:54:04
User entered 'None (0)'	System	29 Sep 2020 23:54:04

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-29T19:53:48', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '7b76f80a-f052-4663-8a3d-00ae5245ee2a'	System	29 Sep 2020 23:54:04
User entered 'None (0)'	System	29 Sep 2020 23:54:04

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-29T19:53:50', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '7b76f80a-f052-4663-8a3d-00ae5245ee2a'	System	29 Sep 2020 23:54:04
User entered 'None (0)'	System	29 Sep 2020 23:54:04

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-29T19:53:56', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '7b76f80a-f052-4663-8a3d-00ae5245ee2a'	System	29 Sep 2020 23:54:04
User entered 'None (0)'	System	29 Sep 2020 23:54:04

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-29T19:53:59', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '7b76f80a-f052-4663-8a3d-00ae5245ee2a'	System	29 Sep 2020 23:54:04
User entered 'No (N)'	System	29 Sep 2020 23:54:04

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-09-29T19:54:03', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '7b76f80a-f052-4663-8a3d-00ae5245ee2a' User entered '29 Sep 2020 19:54'	System	29 Sep 2020 23:54:04
	System	29 Sep 2020 23:54:04

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 13:25:38

US3802046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 13:25:38

US3802046

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
	(b) (4)	
User entered 'Yes (Y)'	Dominic Kramer (b) (4)	01 Oct 2020 13:57:27
	(b) (4)	

US3802046

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
	(b) (4)	
User entered '1 Oct 2020'	Dominic Kramer (b) (4)	01 Oct 2020 13:57:27
	(b) (4)	

US3802046

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dominic Kramer (b) (4)	01 Oct 2020 13:57:27

US3802046

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
	(b) (4)	
User entered empty.	Dominic Kramer (b) (4)	01 Oct 2020 13:57:27
	(b) (4)	

US3802046

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
	(b) (4)	
User entered 'Yes (Y)'	Dominic Kramer (b) (4)	01 Oct 2020 13:57:36
	(b) (4)	

US3802046

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 13:57:36

US3802046

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
	(b) (4)	
User entered 'Yes (Y)'	Emily Dougherty (b) (4)	07 Oct 2020 18:30:12
	(b) (4)	

US3802046

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
	(b) (4)	
User entered '07 Oct 2020'	Emily Dougherty (b) (4)	07 Oct 2020 18:30:12
	(b) (4)	

US3802046

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Emily Dougherty (b) (4)	07 Oct 2020 18:30:12
	(b) (4)	

US3802046

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
	(b) (4)	
User entered empty.	Emily Dougherty (b) (4)	07 Oct 2020 18:30:12
	(b) (4)	

US3802046

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	08 Oct 2020 19:06:29
	(b) (4)	
User entered 'Yes (Y)'	Emily Dougherty (b) (4)	07 Oct 2020 18:30:16
	(b) (4)	

US3802046

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 18:30:16

US3802046

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	15 Oct 2020 19:58:56

US3802046

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020'	Jennifer Nagg (b) (4) (b) (4)	15 Oct 2020 19:58:56

US3802046

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Jennifer Nagg (b) (4) (b) (4)	15 Oct 2020 19:58:56

US3802046

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	15 Oct 2020 19:58:56

US3802046

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	15 Oct 2020 19:59:03

US3802046

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 19:59:03

US3802046

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Carney (b) (4) (b) (4)	21 Oct 2020 12:40:18

US3802046

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '21 Oct 2020'	Emily Carney (b) (4) (b) (4)	21 Oct 2020 12:40:18

US3802046

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Emily Carney (b) (4) (b) (4)	21 Oct 2020 12:40:18

US3802046

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	21 Oct 2020 12:40:18

US3802046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Carney (b) (4) (b) (4)	21 Oct 2020 12:41:14

US3802046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Oct 2020'	Emily Carney (b) (4) (b) (4)	21 Oct 2020 12:41:14

US3802046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '08:11'	Emily Carney (b) (4) (b) (4)	21 Oct 2020 12:41:14

US3802046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '21 Oct 2020 08:11'	System	21 Oct 2020 12:41:14

US3802046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.7' F	Emily Carney (b) (4) (b) (4)	21 Oct 2020 12:41:14

US3802046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Emily Carney (b) (4) (b) (4)	21 Oct 2020 12:41:14

US3802046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Infrared'	Emily Carney (b) (4) (b) (4)	21 Oct 2020 12:41:14

US3802046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '67'	Emily Carney (b) (4) (b) (4)	21 Oct 2020 12:41:14

US3802046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Oct 2020 12:41:14

US3802046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '18'	Emily Carney (b) (4) (b) (4)	21 Oct 2020 12:41:14

US3802046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Oct 2020 12:41:14

US3802046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '112'	Emily Carney (b) (4) (b) (4)	21 Oct 2020 12:41:14

US3802046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 12:41:14

US3802046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '74'	Emily Carney (b) (4) (b) (4)	21 Oct 2020 12:41:14

US3802046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 12:41:14

US3802046

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Carney (b) (4) (b) (4)	21 Oct 2020 12:42:12

US3802046

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Emily Carney (b) (4) (b) (4)	21 Oct 2020 12:42:12

US3802046

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Carney (b) (4) (b) (4)	21 Oct 2020 12:42:25

US3802046

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Oct 2020'	Emily Carney (b) (4) (b) (4)	21 Oct 2020 12:42:25

US3802046

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '08:22'	Emily Carney (b) (4) (b) (4)	21 Oct 2020 12:42:25

US3802046

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '21 Oct 2020 08:22'	System	21 Oct 2020 12:42:25

US3802046

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Carney (b) (4) (b) (4)	21 Oct 2020 12:40:07

US3802046

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 12:40:07

US3802046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:00:58
User entered 'Day 64'	System	26 Aug 2020 20:00:58

US3802046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-10-27T18:25:29', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'ae078226-b4af-41ab-bf3e-9f6447e9de5a'	System	27 Oct 2020 22:27:30
User entered 'No (N)'	System	27 Oct 2020 22:27:30

US3802046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

Have you been exposed to someone with 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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-10-27T18:27:23', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'ae078226-b4af-41ab-bf3e-9f6447e9de5a'	System	27 Oct 2020 22:27:30
User entered 'No (N)'	System	27 Oct 2020 22:27:30

US3802046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-10-27T18:27:27', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'ae078226-b4af-41ab-bf3e-9f6447e9de5a' User entered '27 Oct 2020 18:27:27'	System	27 Oct 2020 22:27:30
	System	27 Oct 2020 22:27:30

US3802046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:00:58
User entered '26 Oct 2020 00:01'	System	26 Aug 2020 20:00:58

US3802046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:00:58
User entered '30 Oct 2020 23:59'	System	26 Aug 2020 20:00:58

US3802046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:00:58
User entered 'Day 71'	System	26 Aug 2020 20:00:58

US3802046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-11-02T20:15:20', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'a8e07392-1e13-4e5a-9d5f-fbffa55cb51'	System	03 Nov 2020 01:15:39
User entered 'No (N)'	System	03 Nov 2020 01:15:39

US3802046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

Have you been exposed to someone with 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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-11-02T20:15:27', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'a8e07392-1e13-4e5a-9d5f-fbffa55cb51'	System	03 Nov 2020 01:15:39
User entered 'No (N)'	System	03 Nov 2020 01:15:39

US3802046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-11-02T20:15:37', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'a8e07392-1e13-4e5a-9d5f-fbffa55cb51'	System	03 Nov 2020 01:15:39
User entered '02 Nov 2020 20:15:37'	System	03 Nov 2020 01:15:39

US3802046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:00:58
User entered '02 Nov 2020 00:01'	System	26 Aug 2020 20:00:58

US3802046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:00:58
User entered '06 Nov 2020 23:59'	System	26 Aug 2020 20:00:58

US3802046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:00:58
User entered 'Day 78'	System	26 Aug 2020 20:00:58

US3802046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-11-09T19:26:16', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'b7e51f7c-d078-47a3-a0db-e849541f989c'	System	10 Nov 2020 00:26:37
User entered 'No (N)'	System	10 Nov 2020 00:26:37

US3802046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

Have you been exposed to someone with 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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-11-09T19:26:25', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'b7e51f7c-d078-47a3-a0db-e849541f989c'	System	10 Nov 2020 00:26:37
User entered 'No (N)'	System	10 Nov 2020 00:26:37

US3802046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-11-09T19:26:32', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: 'b7e51f7c-d078-47a3-a0db-e849541f989c' User entered '09 Nov 2020 19:26:32'	System	10 Nov 2020 00:26:37
	System	10 Nov 2020 00:26:37

US3802046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:00:58
User entered '09 Nov 2020 00:01'	System	26 Aug 2020 20:00:58

US3802046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 20:00:58
User entered '13 Nov 2020 23:59'	System	26 Aug 2020 20:00:58

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '23 Oct 2020 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '27 Oct 2020 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '30 Oct 2020 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '03 Nov 2020 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '06 Nov 2020 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '10 Nov 2020 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '13 Nov 2020 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '17 Nov 2020 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-11-20T13:12:49', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '3f0dbf00-e155-4cab-ab39-0ab9d866b083'	System	20 Nov 2020 18:14:21
User entered 'Yes (Y)'	System	20 Nov 2020 18:14:21

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

Have you been exposed to someone with 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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-11-20T13:13:09', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '3f0dbf00-e155-4cab-ab39-0ab9d866b083' User entered 'Yes (Y)'	System	20 Nov 2020 18:14:21
	System	20 Nov 2020 18:14:21

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-11-20T13:13:14', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '3f0dbf00-e155-4cab-ab39-0ab9d866b083'	System	20 Nov 2020 18:14:21
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Nov 2020 18:14:21

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-11-20T13:13:22', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '3f0dbf00-e155-4cab-ab39-0ab9d866b083'	System	20 Nov 2020 18:14:21
User entered 'Yes (Y)'	System	20 Nov 2020 18:14:21

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-11-20T13:13:50', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '3f0dbf00-e155-4cab-ab39-0ab9d866b083'	System	20 Nov 2020 18:14:21
User entered '1'	System	20 Nov 2020 18:14:21

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-11-20T13:13:50', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '3f0dbf00-e155-4cab-ab39-0ab9d866b083'	System	20 Nov 2020 18:14:21
User entered '0'	System	20 Nov 2020 18:14:21

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-11-20T13:13:50', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '3f0dbf00-e155-4cab-ab39-0ab9d866b083'	System	20 Nov 2020 18:14:21
User entered '1'	System	20 Nov 2020 18:14:21

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-11-20T13:13:50', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '3f0dbf00-e155-4cab-ab39-0ab9d866b083' User entered '0'	System	20 Nov 2020 18:14:21
	System	20 Nov 2020 18:14:21

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-11-20T13:13:50', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '3f0dbf00-e155-4cab-ab39-0ab9d866b083'	System	20 Nov 2020 18:14:21
User entered '0'	System	20 Nov 2020 18:14:21

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-11-20T13:13:50', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '3f0dbf00-e155-4cab-ab39-0ab9d866b083'	System	20 Nov 2020 18:14:21
User entered '1'	System	20 Nov 2020 18:14:21

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-11-20T13:13:50', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '3f0dbf00-e155-4cab-ab39-0ab9d866b083'	System	20 Nov 2020 18:14:21
User entered '1'	System	20 Nov 2020 18:14:21

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-11-20T13:13:50', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '3f0dbf00-e155-4cab-ab39-0ab9d866b083'	System	20 Nov 2020 18:14:21
User entered '1'	System	20 Nov 2020 18:14:21

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-11-20T13:13:50', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '3f0dbf00-e155-4cab-ab39-0ab9d866b083'	System	20 Nov 2020 18:14:21
User entered '1'	System	20 Nov 2020 18:14:21

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-11-20T13:13:50', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '3f0dbf00-e155-4cab-ab39-0ab9d866b083' User entered '0'	System	20 Nov 2020 18:14:21
	System	20 Nov 2020 18:14:21

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-11-20T13:13:50', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '3f0dbf00-e155-4cab-ab39-0ab9d866b083'	System	20 Nov 2020 18:14:21
User entered '0'	System	20 Nov 2020 18:14:21

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-11-20T13:13:50', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '3f0dbf00-e155-4cab-ab39-0ab9d866b083'	System	20 Nov 2020 18:14:21
User entered '0'	System	20 Nov 2020 18:14:21

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-11-20T13:13:50', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '3f0dbf00-e155-4cab-ab39-0ab9d866b083'	System	20 Nov 2020 18:14:21
User entered '1'	System	20 Nov 2020 18:14:21

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-11-20T13:13:50', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '3f0dbf00-e155-4cab-ab39-0ab9d866b083'	System	20 Nov 2020 18:14:21
User entered '1'	System	20 Nov 2020 18:14:21

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-11-20T13:13:50', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '3f0dbf00-e155-4cab-ab39-0ab9d866b083'	System	20 Nov 2020 18:14:21
User entered '1'	System	20 Nov 2020 18:14:21

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-11-20T13:13:50', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '3f0dbf00-e155-4cab-ab39-0ab9d866b083' User entered '0'	System	20 Nov 2020 18:14:21
	System	20 Nov 2020 18:14:21

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-11-20T13:13:50', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '3f0dbf00-e155-4cab-ab39-0ab9d866b083'	System	20 Nov 2020 18:14:21
User entered '1'	System	20 Nov 2020 18:14:21

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Please 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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-11-20T13:13:56', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '3f0dbf00-e155-4cab-ab39-0ab9d866b083'	System	20 Nov 2020 18:14:21
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Nov 2020 18:14:21

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-11-20T13:14:02', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '3f0dbf00-e155-4cab-ab39-0ab9d866b083'	System	20 Nov 2020 18:14:21
User entered 'Yes (Y)'	System	20 Nov 2020 18:14:21

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Please 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 (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-11-20T13:14:05', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '3f0dbf00-e155-4cab-ab39-0ab9d866b083'	System	20 Nov 2020 18:14:21
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Nov 2020 18:14:21

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71149D28-7A2B-476B-800F-6AF0DBA2C4DC)', Time: '2020-11-20T13:14:10', User OID: 'PatientReportedOutcome (US3802046)', ODM File OID: '3f0dbf00-e155-4cab-ab39-0ab9d866b083' User entered '20 Nov 2020 13:14:10'	System	20 Nov 2020 18:14:21
	System	20 Nov 2020 18:14:21

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '28 Oct 2022 00:01'	System	19 Nov 2020 18:28:08

US3802046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:28:08
Amendment Manager: User entered '01 Nov 2022 23:59'	System	19 Nov 2020 18:28:08

US3802046

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lalicia Roman (b) (4) (b) (4)	18 Nov 2020 19:46:57

US3802046

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '18 Nov 2020'	Lalicia Roman (b) (4) (b) (4)	18 Nov 2020 19:46:57

US3802046

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Lalicia Roman (b) (4) (b) (4)	18 Nov 2020 19:46:57

US3802046

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Lalicia Roman (b) (4) (b) (4)	18 Nov 2020 19:46:57

US3802046

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lalicia Roman (b) (4) (b) (4)	18 Nov 2020 19:47:00

US3802046

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 19:47:00

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:20:44

[Date of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:48:20
User entered '13 Nov 2020'	Jennifer Nagg (b) (4)	13 Nov 2020 20:56:19
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:20:44

[Time of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:48:20
User entered '10:25'	Jennifer Nagg (b) (4)	13 Nov 2020 20:56:19
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:20:44

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Nov 2020 10:25'	System	13 Nov 2020 20:56:19

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:20:44

[Type of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:48:20
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Jennifer Nagg (b) (4)	13 Nov 2020 20:56:19
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:20:44

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:48:20
User entered 'Yes (Y)'	Jennifer Nagg (b) (4)	13 Nov 2020 20:56:19
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:20:44

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 20:59:34

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:20:44

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:48:54
User entered '13 Nov 2020'	Jennifer Nagg (b) (4)	13 Nov 2020 20:59:34
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:20:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:48:56
User entered '0'	Jennifer Nagg (b) (4)	13 Nov 2020 20:59:34
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:20:44

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:09:40
User entered '98'	Jennifer Nagg (b) (4)	13 Nov 2020 20:59:34
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:20:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	13 Nov 2020 20:59:34

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:20:44

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:49:25
User entered '100.2' F	Jennifer Nagg (b) (4)	13 Nov 2020 20:59:34
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:20:44

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:09:56
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4)	13 Nov 2020 20:59:34
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:20:44

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:09:58
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4)	13 Nov 2020 20:59:34
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:20:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:10:04
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4)	13 Nov 2020 20:59:34
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:20:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:10:16
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 20:10:13
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:10:09
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4)	13 Nov 2020 20:59:34

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:20:44

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:10:19
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4)	13 Nov 2020 20:59:34
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:20:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:10:23
User entered 'Severe (Severe)'	Jennifer Nagg (b) (4)	13 Nov 2020 20:59:34
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:20:44

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:10:26
User entered 'Severe (Severe)'	Jennifer Nagg (b) (4)	13 Nov 2020 20:59:34
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:20:44

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:10:28
User entered 'Severe (Severe)'	Jennifer Nagg (b) (4)	13 Nov 2020 20:59:34
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:20:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:10:32
User entered 'None (None)'	Jennifer Nagg (b) (4)	13 Nov 2020 20:59:34
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:20:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:10:34
User entered 'None (None)'	Jennifer Nagg (b) (4)	13 Nov 2020 20:59:34
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:20:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:10:39
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4)	13 Nov 2020 20:59:34
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:20:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:10:45
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4)	13 Nov 2020 20:59:34
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:20:44

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:10:50
User entered 'None (None)'	Jennifer Nagg (b) (4)	13 Nov 2020 20:59:34
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:20:44

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:10:55
User entered 'None (None)'	Jennifer Nagg (b) (4)	13 Nov 2020 20:59:34
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:20:44

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:10:58
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4)	13 Nov 2020 20:59:34
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:20:44

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:11:01
User entered 'None (None)'	Jennifer Nagg (b) (4)	13 Nov 2020 20:59:34
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:20:44

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:53:01

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:20:44

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:11:18
User entered '14 Nov 2020'	Emily Carney (b) (4)	16 Nov 2020 15:53:01
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:20:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:12:20
User entered '0'	Emily Carney (b) (4)	16 Nov 2020 15:53:01
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:20:44

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:11:24
User entered '94'	Emily Carney (b) (4)	16 Nov 2020 15:53:01
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:20:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	16 Nov 2020 15:53:01

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:20:44

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:11:26
User entered '101' F	Emily Carney (b) (4)	16 Nov 2020 15:53:01
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:20:44

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:11:28
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:53:01
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:20:44

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:11:33
User entered 'Moderate (Moderate)'	Emily Carney (b) (4)	16 Nov 2020 15:53:01
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:20:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:11:38
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:53:01
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:20:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:11:42
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:53:01
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:20:44

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:11:46
User entered 'Severe (Severe)'	Emily Carney (b) (4)	16 Nov 2020 15:53:01
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:20:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:11:49
User entered 'Mild (Mild)'	Emily Carney (b) (4)	16 Nov 2020 15:53:01
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:20:44

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:11:50
User entered 'Mild (Mild)'	Emily Carney (b) (4)	16 Nov 2020 15:53:01
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:20:44

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:11:54
User entered 'Moderate (Moderate)'	Emily Carney (b) (4)	16 Nov 2020 15:53:01
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:20:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:11:56
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:53:01
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:20:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:11:58
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:53:01
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:20:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:12:04
User entered 'Moderate (Moderate)'	Emily Carney (b) (4)	16 Nov 2020 15:53:01
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:20:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:12:09
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:53:01
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:20:44

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:12:16
User entered 'Mild (Mild)'	Emily Carney (b) (4)	16 Nov 2020 15:53:01
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:20:44

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:12:20
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:53:01
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:20:44

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:12:23
User entered 'Severe (Severe)'	Emily Carney (b) (4)	16 Nov 2020 15:53:01
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:20:44

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:12:27
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:53:01
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:20:44

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:54:27

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:20:44

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:12:41
User entered '15 Nov 2020'	Emily Carney (b) (4)	16 Nov 2020 15:54:27
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:20:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:12:42
User entered '0'	Emily Carney (b) (4)	16 Nov 2020 15:54:27
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:20:44

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:12:46
User entered '96'	Emily Carney (b) (4)	16 Nov 2020 15:54:27
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:20:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	16 Nov 2020 15:54:27

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:20:44

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:12:47
User entered '98.0' F	Emily Carney (b) (4)	16 Nov 2020 15:54:27
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:20:44

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:13:05
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:54:27
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:20:44

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:13:15
User entered 'Mild (Mild)'	Emily Carney (b) (4)	16 Nov 2020 15:54:27
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:20:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:13:19
User entered 'Mild (Mild)'	Emily Carney (b) (4)	16 Nov 2020 15:54:27
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:20:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:13:22
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:54:27
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:20:44

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:13:26
User entered 'Severe (Severe)'	Emily Carney (b) (4)	16 Nov 2020 15:54:27
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:20:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:13:29
User entered 'Moderate (Moderate)'	Emily Carney (b) (4)	16 Nov 2020 15:54:27
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:20:44

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:13:30
User entered 'Moderate (Moderate)'	Emily Carney (b) (4)	16 Nov 2020 15:54:27
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:20:44

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:13:33
User entered 'Moderate (Moderate)'	Emily Carney (b) (4)	16 Nov 2020 15:54:27
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:20:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:13:35
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:54:27
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:20:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:13:37
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:54:27
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:20:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:13:40
User entered 'Mild (Mild)'	Emily Carney (b) (4)	16 Nov 2020 15:54:27
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:20:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:13:43
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:54:27
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:20:44

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:13:48
User entered 'Moderate (Moderate)'	Emily Carney (b) (4)	16 Nov 2020 15:54:27
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:20:44

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:13:46
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:54:27
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:20:44

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:13:54
User entered 'Moderate (Moderate)'	Emily Carney (b) (4)	16 Nov 2020 15:54:27
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:20:44

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:13:58
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:54:27
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:20:44

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 16:42:43

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:20:44

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:14:14
User entered '16 Nov 2020'	Jennifer Nagg (b) (4)	17 Nov 2020 16:42:43
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:20:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:14:16
User entered '0'	Jennifer Nagg (b) (4)	17 Nov 2020 16:42:43
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:20:44

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:14:20
User entered '98'	Jennifer Nagg (b) (4)	17 Nov 2020 16:42:43
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:20:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	17 Nov 2020 16:42:43

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:20:44

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:14:23
User entered '98.0' F	Jennifer Nagg (b) (4)	17 Nov 2020 16:42:43
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:20:44

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:14:25
User entered 'None (None)'	Jennifer Nagg (b) (4)	17 Nov 2020 16:42:43
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:20:44

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:14:33
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4)	17 Nov 2020 16:42:43
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:20:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:14:36
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4)	17 Nov 2020 16:42:43
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:20:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:14:40
User entered 'None (None)'	Jennifer Nagg (b) (4)	17 Nov 2020 16:42:43
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:20:44

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:14:45
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4)	17 Nov 2020 16:42:43
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:20:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:14:48
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4)	17 Nov 2020 16:42:43
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:20:44

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:14:49
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4)	17 Nov 2020 16:42:43
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:20:44

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:14:53
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4)	17 Nov 2020 16:42:43
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:20:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:14:59
User entered 'None (None)'	Jennifer Nagg (b) (4)	17 Nov 2020 16:42:43
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:20:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:15:02
User entered 'None (None)'	Jennifer Nagg (b) (4)	17 Nov 2020 16:42:43
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:20:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:15:05
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4)	17 Nov 2020 16:42:43
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:20:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:15:11
User entered 'None (None)'	Jennifer Nagg (b) (4)	17 Nov 2020 16:42:43
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:20:44

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:15:20
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4)	17 Nov 2020 16:42:43
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:20:44

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:15:22
User entered 'None (None)'	Jennifer Nagg (b) (4)	17 Nov 2020 16:42:43
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:20:44

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:15:26
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4)	17 Nov 2020 16:42:43
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:20:44

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:15:31
User entered 'None (None)'	Jennifer Nagg (b) (4)	17 Nov 2020 16:42:43
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:20:44

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:41:10

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:20:44

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:16:09
User entered '17 Nov 2020'	Jennifer Nagg (b) (4)	17 Nov 2020 19:41:10
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:20:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:16:11
User entered '0'	Jennifer Nagg (b) (4)	17 Nov 2020 19:41:10
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:20:44

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:16:15
User entered '98'	Jennifer Nagg (b) (4)	17 Nov 2020 19:41:10
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:20:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	17 Nov 2020 19:41:10

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:20:44

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:16:17
User entered '97.7' F	Jennifer Nagg (b) (4)	17 Nov 2020 19:41:10
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:20:44

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:16:23
User entered 'None (None)'	Jennifer Nagg (b) (4)	17 Nov 2020 19:41:10
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:20:44

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:16:31
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4)	17 Nov 2020 19:41:10
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:20:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:16:34
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4)	17 Nov 2020 19:41:10
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:20:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:16:39
User entered 'None (None)'	Jennifer Nagg (b) (4)	17 Nov 2020 19:41:10
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:20:44

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:16:53
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4)	17 Nov 2020 19:41:10
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:20:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:16:58
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4)	17 Nov 2020 19:41:10
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:20:44

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:17:00
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4)	17 Nov 2020 19:41:10
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:20:44

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:17:02
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4)	17 Nov 2020 19:41:10
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:20:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:17:06
User entered 'None (None)'	Jennifer Nagg (b) (4)	17 Nov 2020 19:41:10
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:20:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:17:08
User entered 'None (None)'	Jennifer Nagg (b) (4)	17 Nov 2020 19:41:10
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:20:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
User closed query 'source states "moderate" . please confirm ' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 16:12:49
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:12:47
Query 'source states "moderate" . please confirm ' answered with 'confirmed that status is moderate' (Site from CRA).	Emily Dougherty (b) (4)	19 Nov 2020 14:59:05
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Emily Dougherty (b) (4)	19 Nov 2020 14:58:51
User opened query 'source states "moderate" . please confirm ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 20:17:45
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4)	17 Nov 2020 19:41:10

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:20:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:17:50
User entered 'None (None)'	Jennifer Nagg (b) (4)	17 Nov 2020 19:41:10
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:20:44

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:17:53
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4)	17 Nov 2020 19:41:10
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:20:44

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:17:55
User entered 'None (None)'	Jennifer Nagg (b) (4)	17 Nov 2020 19:41:10
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:20:44

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:17:59
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4)	17 Nov 2020 19:41:10
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:20:44

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:18:02
User entered 'None (None)'	Jennifer Nagg (b) (4)	17 Nov 2020 19:41:10
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:20:44

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)'	Emily Dougherty (b) (4) (b) (4)	19 Nov 2020 15:05:22

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:20:44

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:30:23
User entered '18 Nov 2020'	Emily Dougherty (b) (4)	19 Nov 2020 15:05:22
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:20:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:30:29
User entered '0'	Emily Dougherty (b) (4)	19 Nov 2020 15:05:22
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:20:44

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:30:26
User entered '98'	Emily Dougherty (b) (4)	19 Nov 2020 15:05:22
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:20:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Nov 2020 15:05:22

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:20:44

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:30:32
User entered '98.9' F	Emily Dougherty (b) (4)	19 Nov 2020 15:05:22
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:20:44

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:30:36
User entered 'None (None)'	Emily Dougherty (b) (4)	19 Nov 2020 15:05:22
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:20:44

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:30:42
User entered 'Mild (Mild)'	Emily Dougherty (b) (4)	19 Nov 2020 15:05:22
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:20:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:30:46
User entered 'None (None)'	Emily Dougherty (b) (4)	19 Nov 2020 15:05:22
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:20:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:30:49
User entered 'None (None)'	Emily Dougherty (b) (4)	19 Nov 2020 15:05:22
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:20:44

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:30:54
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4)	19 Nov 2020 15:05:22
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:20:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:30:56
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4)	19 Nov 2020 15:05:22
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:20:44

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:30:59
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4)	19 Nov 2020 15:05:22
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:20:44

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:31:05
User entered 'Mild (Mild)'	Emily Dougherty (b) (4)	19 Nov 2020 15:05:22
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:20:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:31:07
User entered 'None (None)'	Emily Dougherty (b) (4)	19 Nov 2020 15:05:22
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:20:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:31:09
User entered 'None (None)'	Emily Dougherty (b) (4)	19 Nov 2020 15:05:22
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:20:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:31:11
User entered 'None (None)'	Emily Dougherty (b) (4)	19 Nov 2020 15:05:22
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:20:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:31:18
User entered 'None (None)'	Emily Dougherty (b) (4)	19 Nov 2020 15:05:22
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:20:44

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:31:26
User entered 'Mild (Mild)'	Emily Dougherty (b) (4)	19 Nov 2020 15:05:22
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:20:44

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:31:29
User entered 'None (None)'	Emily Dougherty (b) (4)	19 Nov 2020 15:05:22
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:20:44

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:31:33
User entered 'Severe (Severe)'	Emily Dougherty (b) (4)	19 Nov 2020 15:05:22
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:20:44

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:31:36
User entered 'None (None)'	Emily Dougherty (b) (4)	19 Nov 2020 15:05:22
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:20:44

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:16:38

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:20:44

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:34:24
User entered '19 Nov 2020'	Emily Dougherty (b) (4)	23 Nov 2020 17:16:38
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:20:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:34:29
User entered '0'	Emily Dougherty (b) (4)	23 Nov 2020 17:16:38
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:20:44

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:34:30
User entered '98'	Emily Dougherty (b) (4)	23 Nov 2020 17:16:38
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:20:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	23 Nov 2020 17:16:38

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:20:44

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:34:32
User entered '97.9' F	Emily Dougherty (b) (4)	23 Nov 2020 17:16:38
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:20:44

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:34:37
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 17:16:38
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:20:44

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:34:40
User entered 'Mild (Mild)'	Emily Dougherty (b) (4)	23 Nov 2020 17:16:38
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:20:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:34:46
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 17:16:38
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:20:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:34:48
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 17:16:38
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:20:44

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:34:50
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:16:38

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:20:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:34:54
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4)	23 Nov 2020 17:16:38
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:20:44

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:34:57
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4)	23 Nov 2020 17:16:38
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:20:44

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:35:01
User entered 'Mild (Mild)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:16:38

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:20:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:35:04
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 17:16:38
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:20:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:35:05
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 17:16:38
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:20:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:35:09
User entered 'Mild (Mild)'	Emily Dougherty (b) (4)	23 Nov 2020 17:16:38
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:20:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:35:20
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 17:16:38
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:20:44

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:35:26
User entered 'Mild (Mild)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:16:38

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:20:44

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:35:28
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 17:16:38
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:20:44

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:35:31
User entered 'Mild (Mild)'	Emily Dougherty (b) (4)	23 Nov 2020 17:16:38
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:20:44

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:35:35
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 17:16:38
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:20:44

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:17:34

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:20:44

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:35:59
User entered '20 Nov 2020'	Emily Dougherty (b) (4)	23 Nov 2020 17:17:34
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:20:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:36:01
User entered '0'	Emily Dougherty (b) (4)	23 Nov 2020 17:17:34
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:20:44

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:36:03
User entered '97'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:17:34

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:20:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	23 Nov 2020 17:17:34

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:20:44

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:36:04
User entered '99.1' F	Emily Dougherty (b) (4)	23 Nov 2020 17:17:34
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:20:44

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:36:06
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 17:17:34
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:20:44

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:36:08
User entered 'Mild (Mild)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:17:34

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:20:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:36:11
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 17:17:34
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:20:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:36:13
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 17:17:34
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:20:44

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:36:16
User entered 'Mild (Mild)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:17:34

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:20:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:36:18
User entered 'Mild (Mild)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:17:34

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:20:44

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:36:20
User entered 'Mild (Mild)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:17:34

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:20:44

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:36:23
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 17:17:34
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:20:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:36:29
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 17:17:34
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:20:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:36:31
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 17:17:34
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:20:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:36:36
User entered 'Mild (Mild)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:17:34

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:20:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:36:45
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 17:17:34
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:20:44

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:36:49
User entered 'Mild (Mild)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:17:34

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:20:44

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:36:51
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 17:17:34
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:20:44

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:36:54
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 17:17:34
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:20:44

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:36:56
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 17:17:34
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:20:44

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:19:11

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:20:44

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:37:38
User entered '21 Nov 2020'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:19:11

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:20:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:37:39
User entered '0'	Emily Dougherty (b) (4)	23 Nov 2020 17:19:11
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:20:44

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:37:42
User entered '96'	Emily Dougherty (b) (4)	23 Nov 2020 17:19:11
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:20:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	23 Nov 2020 17:19:11

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:20:44

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:37:43
User entered '99' F	Emily Dougherty (b) (4)	23 Nov 2020 17:19:11
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:20:44

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:37:46
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 17:19:11
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:20:44

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:37:48
User entered 'Mild (Mild)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:19:11

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:20:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:37:49
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:19:11

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:20:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:37:51
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 17:19:11
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:20:44

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:37:53
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:19:11

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:20:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:37:56
User entered 'Mild (Mild)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:19:11

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:20:44

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:37:58
User entered 'Mild (Mild)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:19:11

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:20:44

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:00
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 17:19:11
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:20:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:01
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 17:19:11
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:20:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:03
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 17:19:11
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:20:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:10
User entered 'Mild (Mild)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:19:11

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:20:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:12
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 17:19:11
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:20:44

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:17
User entered 'Mild (Mild)'	Emily Dougherty (b) (4)	23 Nov 2020 17:19:11
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:20:44

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:20
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 17:19:11
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:20:44

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:24
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 17:19:11
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:20:44

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:38:23
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 17:19:11
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:20:44

[Date of Visit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:23:42
User entered '13 Nov 2020'	Jennifer Nagg (b) (4)	13 Nov 2020 21:00:06
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:20:44

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:23:42
User entered 'Yes (Y)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:00:06
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:20:44

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:23:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	18 Nov 2020 04:37:03
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	18 Nov 2020 04:37:01
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'done' (Site from System).	Jennifer Nagg (b) (4)	13 Nov 2020 21:17:58
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	13 Nov 2020 21:17:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	13 Nov 2020 21:17:07
Query 'Data is required. Please complete.' answered with 'pending' (Site from System).	Jennifer Nagg (b) (4)	13 Nov 2020 21:00:24
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 21:00:06
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:00:06

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Form: COVID Diagnostic Test

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[Date of Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:23:42
User entered '13 Nov 2020'	Jennifer Nagg (b) (4)	13 Nov 2020 21:00:06
	(b) (4)	

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[Type of Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:23:42
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:00:06
	(b) (4)	

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[Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:23:42
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:00:06
	(b) (4)	

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[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:23:42
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:00:06
	(b) (4)	

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:23:42
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:00:06
	(b) (4)	

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[CLIA Certified?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:23:42
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:00:06
	(b) (4)	

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 21:17:07

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Folder: Covid-19 Assessment 13 Nov 2020

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Did the subject have Respiratory Rates $\geq$ 30 per Minute?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:20:44

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:20:44

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

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[Respiratory Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:20:44

Did the subject have Heart Rate $\geq$ 125 beats per minute

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:20:44

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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[Heart Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

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Did the subject have Oxygen Saturation of SpO2 $\leq$ 93% on room air at sea level?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:20:44

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:20:44

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:20:44

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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[PaO2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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[ECMO?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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[Clinical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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[Radiographical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

US3802046

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Generated On: 26 Nov 2020 11:20:44

[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

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[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

US3802046

Folder: Covid-19 Assessment 13 Nov 2020

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:08
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:18:57
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:20:44

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Jennifer Nagg (b) (4) (b) (4)	20 Nov 2020 16:27:20

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:20:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:40:06
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	20 Nov 2020 16:27:20

US3802046

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:20:44

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:40:09
User entered '15 Nov 2020'	Jennifer Nagg (b) (4) (b) (4)	20 Nov 2020 16:27:20

US3802046

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 11:20:44

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Jennifer Nagg (b) (4) (b) (4)	20 Nov 2020 16:27:20

US3802046

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 11:20:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:40:15
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	20 Nov 2020 16:27:20

US3802046

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 11:20:44

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:40:17
User entered '17 Nov 2020'	Jennifer Nagg (b) (4) (b) (4)	20 Nov 2020 16:27:20

US3802046

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 11:20:44

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Jennifer Nagg (b) (4) (b) (4)	20 Nov 2020 16:27:20

US3802046

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 11:20:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:40:30
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	20 Nov 2020 16:27:20

US3802046

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 11:20:44

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:40:31
User entered '19 Nov 2020'	Jennifer Nagg (b) (4) (b) (4)	20 Nov 2020 16:27:20

US3802046

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:20:44

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Jennifer Nagg (b) (4) (b) (4)	20 Nov 2020 16:27:20

US3802046

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:20:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:40:45
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 19:53:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Nov 2020 19:53:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	23 Nov 2020 19:53:42
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 16:27:20
User entered empty.	Jennifer Nagg (b) (4)	20 Nov 2020 16:27:20

US3802046

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:20:44

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:40:46
User entered '21 Nov 2020' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	23 Nov 2020 19:53:42
User entered empty.	Jennifer Nagg (b) (4)	20 Nov 2020 16:27:20

US3802046

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:20:44

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Jennifer Nagg (b) (4) (b) (4)	20 Nov 2020 16:27:20

US3802046

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:20:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 16:27:20
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	20 Nov 2020 16:27:20

US3802046

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:20:44

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	20 Nov 2020 16:27:20

US3802046

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:20:44

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Jennifer Nagg (b) (4) (b) (4)	20 Nov 2020 16:27:20

US3802046

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:20:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 16:27:20
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	20 Nov 2020 16:27:20

US3802046

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:20:44

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	20 Nov 2020 16:27:20

US3802046

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:20:44

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Jennifer Nagg (b) (4) (b) (4)	20 Nov 2020 16:27:20

US3802046

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:20:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 16:27:20
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	20 Nov 2020 16:27:20

US3802046

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:20:44

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	20 Nov 2020 16:27:20

US3802046

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:31
User entered 'Yes (Y)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:32:25
	(b) (4)	

US3802046

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:31
User entered '13 Nov 2020'	Jennifer Nagg (b) (4)	13 Nov 2020 21:32:25
	(b) (4)	

US3802046

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:24:31
User entered 'Clinic (Clinic)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:32:25
	(b) (4)	

US3802046

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	13 Nov 2020 21:32:25

US3802046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:25:26
User entered 'Yes (Y)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:33:23
	(b) (4)	

US3802046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:26:08
User entered '13 Nov 2020'	Jennifer Nagg (b) (4)	13 Nov 2020 21:33:23
	(b) (4)	

US3802046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Nov 2020 02:30:08
User closed query 'Source states 10:32 , please verify. ' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 21:55:52
Query 'Source states 10:32 , please verify. ' answered with 'updated' (Site from CRA).	Emily Dougherty (b) (4)	20 Nov 2020 21:24:35
User entered '10:32' reason for change: Data Entry Error	(b) (4)	
User entered '10:32' reason for change: Data Entry Error	Emily Dougherty (b) (4)	20 Nov 2020 21:24:30
User entered '10:32' reason for change: Data Entry Error	(b) (4)	
User opened query 'Source states 10:32 , please verify. ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 20:26:30
User entered '10:25'	Jennifer Nagg (b) (4)	13 Nov 2020 21:33:23
	(b) (4)	

US3802046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '13 Nov 2020 10:32'	System	20 Nov 2020 21:24:30
User entered '13 Nov 2020 10:25'	System	13 Nov 2020 21:33:23

US3802046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:25:39
User entered missing code ND - Not Done.	Jennifer Nagg (b) (4)	13 Nov 2020 21:33:23
DataPoint set to visible.	(b) (4) System	13 Nov 2020 21:32:25

US3802046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:25:40
User entered missing code ND - Not Done.	Jennifer Nagg (b) (4)	13 Nov 2020 21:33:23
DataPoint set to visible.	(b) (4) System	13 Nov 2020 21:32:25

US3802046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query ' Per CDM: Temperature and Respiratory rate values are out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 21:22:59
Query ' Per CDM: Temperature and Respiratory rate values are out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate. ' answered with 'CS due to symptomatic COVID-19 AE' (Site from DM).	Dominic Kramer (b) (4) (b) (4)	24 Nov 2020 14:07:51
User opened query ' Per CDM: Temperature and Respiratory rate values are out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 10:39:50
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:25:43
User entered '100.2' F	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 21:33:23

US3802046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:25:45
User entered 'Other (Other)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:33:23
	(b) (4)	

US3802046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:25:47
User closed query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	System	15 Nov 2020 12:39:25
User entered 'infared' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	15 Nov 2020 12:39:25
	(b) (4)	
User opened query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	System	13 Nov 2020 21:33:23
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:33:23
	(b) (4)	

US3802046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:25:51
User entered '82'	Jennifer Nagg (b) (4)	13 Nov 2020 21:33:23
	(b) (4)	

US3802046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Nov 2020 21:33:23

US3802046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:25:55
User entered '22'	Jennifer Nagg (b) (4)	13 Nov 2020 21:33:23
	(b) (4)	

US3802046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Nov 2020 21:33:23

US3802046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:25:58
User entered '107'	Jennifer Nagg (b) (4)	13 Nov 2020 21:33:23
	(b) (4)	

US3802046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Nov 2020 21:33:23

US3802046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:25:59
User entered '83'	Jennifer Nagg (b) (4)	13 Nov 2020 21:33:23
	(b) (4)	

US3802046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Nov 2020 21:33:23

US3802046

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:26:46
User entered 'Yes (Y)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:32:34
	(b) (4)	

US3802046

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:26:46
User entered '13 Nov 2020'	Jennifer Nagg (b) (4)	13 Nov 2020 21:32:34
	(b) (4)	

US3802046

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 11:20:44

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:27:38
User entered 'Yes (Y)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:33:36
	(b) (4)	

US3802046

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 11:20:44

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:27:38
User entered '13 Nov 2020'	Jennifer Nagg (b) (4)	13 Nov 2020 21:33:36
	(b) (4)	

US3802046

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:20:44

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:41
User entered 'Yes (Y)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:00:48
	(b) (4)	

US3802046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:30:55
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:37
User entered 'USA-US098-2020-mRNA-1273-P301000005'	System	16 Nov 2020 20:39:33
User entered 'New'	(b) (4), (b) (6)	16 Nov 2020 20:39:33

US3802046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please update the term as "Symptomatic COVID-19" as "Is this event a confirmed diagnosis of Symptomatic Covid-19?" is recorded Yes (Refer CCG Page 35-36). Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 22:06:26
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)	20 Nov 2020 16:46:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	20 Nov 2020 16:46:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:24:42
Data point term sent to Coder	System	20 Nov 2020 16:15:14
Query 'Per CDM: Please update the term as "Symptomatic COVID-19" as "Is this event a confirmed diagnosis of Symptomatic Covid-19?" is recorded Yes (Refer CCG Page 35-36). Thank you.' answered with 'updated' (Site from DM).	Lalicia Roman (b) (4)	20 Nov 2020 16:15:14
DataPoint Un-verified.	(b) (4)	
Coding entries removed.	Lalicia Roman (b) (4)	20 Nov 2020 16:15:06
User entered 'Symptomatic COVID 19' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per CDM: Please update the term as "Symptomatic COVID-19" as "Is this event a confirmed diagnosis of Symptomatic Covid-19?" is recorded Yes (Refer CCG Page 35-36). Thank you.' (Site from DM).	Lalicia Roman (b) (4)	20 Nov 2020 16:15:06
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 11:20:39
	(b) (4), (b) (6)	18 Nov 2020 20:30:56
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)	13 Nov 2020 21:04:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	13 Nov 2020 21:04:34
Data point term sent to Coder	System	13 Nov 2020 21:03:42

US3802046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'COVID 19'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 21:03:36

US3802046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:30:58
User entered 'Yes (Y)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:03:36
	(b) (4)	

US3802046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:31:00
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:03:36
	(b) (4)	

US3802046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:31:01
User entered 'Yes (Y)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:03:36
	(b) (4)	

US3802046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Source states 13nov2020. please confirm' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 16:24:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:24:48
Query 'Source states 13nov2020. please confirm' answered with 'error correction' (Site from CRA).	Jennifer Nagg (b) (4)	19 Nov 2020 18:22:51
User entered '13 Nov 2020' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	19 Nov 2020 18:22:39
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 20:31:50
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:31:47
User opened query 'Source states 13nov2020. please confirm' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 20:30:51
User entered '12 Nov 2020'	Jennifer Nagg (b) (4)	13 Nov 2020 21:03:36

US3802046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:31:05
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:03:36
	(b) (4)	

US3802046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 21:03:36

US3802046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:31:07
User entered 'Yes (Y)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:03:36
	(b) (4)	

US3802046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:13:41
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:31:09
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 21:03:36

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:31:10
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:03:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 21:03:36

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Folder: Adverse Events

Form: Adverse Events (1)

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:05:09
DataPoint Un-verified.	Jennifer Nagg (b) (4)	23 Nov 2020 19:45:16
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jennifer Nagg (b) (4)	23 Nov 2020 19:45:16
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:31:12
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:03:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:05:11
DataPoint Un-verified.	Jennifer Nagg (b) (4)	23 Nov 2020 19:45:16
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	23 Nov 2020 19:45:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:31:15
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:03:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:31:16
User entered '0'	Jennifer Nagg (b) (4)	13 Nov 2020 21:03:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:31:23
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 20:31:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:31:18
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 21:03:36

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:05:16
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).		24 Nov 2020 16:14:40
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		24 Nov 2020 16:14:40
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	23 Nov 2020 19:45:16
DataPoint Un-verified.	Jennifer Nagg (b) (4)	23 Nov 2020 19:45:16
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Jennifer Nagg (b) (4)	23 Nov 2020 19:45:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:31:21
User entered '0'	Jennifer Nagg (b) (4)	13 Nov 2020 21:03:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:05:19
DataPoint Un-verified.	Jennifer Nagg (b) (4)	23 Nov 2020 19:45:16
	(b) (4)	
User entered '21 Nov 2020' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	23 Nov 2020 19:45:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:31:25
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:03:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:05:21
DataPoint Un-verified.	Melissa Andrasko (b) (4)	24 Nov 2020 16:14:40
User entered '23 Nov 2020' reason for change: Data Entry Error	Melissa Andrasko (b) (4)	24 Nov 2020 16:14:40
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:31:26
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:03:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:05:24
DataPoint Un-verified.	Jennifer Nagg (b) (4)	23 Nov 2020 19:45:16
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	23 Nov 2020 19:45:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:31:28
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:03:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:31:30
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:03:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:31:32
User entered '0'	Jennifer Nagg (b) (4)	13 Nov 2020 21:03:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:31:47
User entered '0'	Jennifer Nagg (b) (4)	13 Nov 2020 21:03:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:31:47
User entered '0'	Jennifer Nagg (b) (4)	13 Nov 2020 21:03:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:31:34
User entered 'Not Related (NOT RELATED)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:03:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:31:35
User entered 'Not Related (NOT RELATED)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:03:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:31:37
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Nagg (b) (4)	13 Nov 2020 21:03:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:51:26
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).		24 Nov 2020 16:14:40
DataPoint Un-verified.	Melissa Andrasko (b) (4)	24 Nov 2020 16:14:40
User entered '0' reason for change: Data Entry Error	Melissa Andrasko (b) (4)	24 Nov 2020 16:14:40
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	23 Nov 2020 19:45:16
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:31:47
User entered '1'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 21:03:36

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:06:12
DataPoint Un-verified.	Jennifer Nagg (b) (4)	23 Nov 2020 19:45:16
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	23 Nov 2020 19:45:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:31:47
User entered '0'	Jennifer Nagg (b) (4)	13 Nov 2020 21:03:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:31:47
User entered '0'	Jennifer Nagg (b) (4)	13 Nov 2020 21:03:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:07:06
DataPoint Un-verified.	Melissa Andrasko (b) (4)	24 Nov 2020 16:15:38
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Melissa Andrasko (b) (4)	24 Nov 2020 16:15:38
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)	20 Nov 2020 17:14:00
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:31:47
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 21:03:36

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Folder: Adverse Events

Form: Adverse Events (1)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:31:47
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 21:03:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:06:19
User entered '70 year old subject who began to experience worsening shortness of breath and cough with COVID19. Presented to ED for evaluation on 11/21/2020 and was admitted. 11/21/2020: Compared with previous ECG and unchanged without evidence of acute ischemia or arrhythmia, CXR:1 view chest x-ray, per my interpretation: Normal heart and mediastinum without infiltrate or pneumothorax, No evidence for pneumonia or pulmonary edema on frontal chest radiograph . CT angiography of the chest performed to evaluate for pulmonary embolism/Covid and read by radiology as: "Impression: No acute pulmonary embolus or aortic dissection. Multiple subpleural mixed interstitial and groundglass opacity in both lung predominantly in the lung bases, consistent with the known COVID 19 infection." Subject did not meet criteria for Remdesivir and did not require any supplemental oxygen. 11/22/2020- 37.1, 88, 125/81, 97-99% room air 11/23/2020- 36.7, 70, 18, 114/72, 95-96% room air, discharged to home, clinically improved.' reason for change: Data Entry Error	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:25:07
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)	24 Nov 2020 19:06:13
User closed query 'PV Query: Please clarify whether the subject had an occupational risk, location and living/circumstances risk, or known opportunity of exposure to SARS-COV-2.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:06:06

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Folder: Adverse Events

Form: Adverse Events (1)

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[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 'Updated ' (Site from Safety).	Melissa Andrasko (b) (4)	24 Nov 2020 16:16:50
Query 'PV Query: Please clarify whether the subject had an occupational risk, location and living/circumstances risk, or known opportunity of exposure to SARS-COV-2.' answered with 'Occupational ' (Site from Safety).	Melissa Andrasko (b) (4)	24 Nov 2020 16:16:41
User entered 'IV DEXAMETHASONE THEN PLACED ON ORACLE DEXAMETHASONE UPON DISCHARGE. Participant is a physician.' reason for change: Data Entry Error	Melissa Andrasko (b) (4)	24 Nov 2020 16:16:13
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	24 Nov 2020 16:14:40
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	24 Nov 2020 16:14:40
DataPoint Un-verified.	Melissa Andrasko (b) (4)	24 Nov 2020 16:14:40
User entered 'IV dexamethasone then placed on oracle dexamethasone upon discharge' reason for change: Data Entry Error	Melissa Andrasko (b) (4)	24 Nov 2020 16:14:40
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	23 Nov 2020 19:45:16
User opened query 'PV Query: Please clarify whether the subject had an occupational risk, location and living/circumstances risk, or known opportunity of exposure to SARS-COV-2.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:15:01

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[Narrative](#)

Audit	User	Time (GMT)
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)	20 Nov 2020 17:14:15
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:31:47
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 21:03:36

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Folder: Adverse Events

Form: Adverse Events (1)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 19:45:16
User entered '0'	System	13 Nov 2020 21:03:36

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Folder: Adverse Events

Form: Adverse Events (1)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 21:03:36

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Folder: Adverse Events

Form: Adverse Events (1)

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

Audit	User	Time (GMT)
User entered '0'	System	23 Nov 2020 19:45:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:20:44

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:32:04
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'Yes (Y)'	Lalicia Roman (b) (4)	26 Aug 2020 19:50:53
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:37:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: AZASPIRODECANEDIONE DERIVATIVES, PRODUCT: BUSPIRONE HYDROCHLORIDE, PRODUCTSYNONYM: BUSPAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 19:40:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 19:40:43
Data point term sent to Coder Coding entries removed.	System	20 Oct 2020 19:39:37
	Emily Carney (b) (4)	20 Oct 2020 19:38:40
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: AZASPIRODECANEDIONE DERIVATIVES, PRODUCT: BUSPIRONE HYDROCHLORIDE, PRODUCTSYNONYM: BUSPAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 18:12:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 18:12:21
Data point term sent to Coder User entered 'Buspar'	System	26 Aug 2020 19:56:51
	Lalicia Roman (b) (4)	26 Aug 2020 19:56:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:37:38
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'No (N)'	Lalicia Roman (b) (4)	26 Aug 2020 19:56:33
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:37:40
User closed query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 07:44:43
Query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' answered with 'Anxiety has been added to Med History ' (Site from DM).	Emily Carney (b) (4)	20 Oct 2020 19:39:32
Signature has been broken.	(b) (4)	20 Oct 2020 19:38:40
User entered 'ANXIETY' reason for change: Data Entry Error	Emily Carney (b) (4)	20 Oct 2020 19:38:40
User opened query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 13:37:20
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'mild anxiety'	Lalicia Roman (b) (4)	26 Aug 2020 19:56:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:37:43
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'unknown'	Lalicia Roman (b) (4)	26 Aug 2020 19:56:33
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:37:46
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'mg (mg)'	Lalicia Roman (b) (4)	26 Aug 2020 19:56:33
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:37:48
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered empty.	Lalicia Roman (b) (4)	26 Aug 2020 19:56:33
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:37:50
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'once daily (QD)'	Lalicia Roman (b) (4)	26 Aug 2020 19:56:33
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:37:53
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered empty.	Lalicia Roman (b) (4)	26 Aug 2020 19:56:33
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:37:55
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'Oral (ORAL)'	Lalicia Roman (b) (4)	26 Aug 2020 19:56:33
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:37:57
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered empty.	Lalicia Roman (b) (4)	26 Aug 2020 19:56:33
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:37:59
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'UN UNK 2005'	Lalicia Roman (b) (4)	26 Aug 2020 19:56:33
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:38:01
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered '0'	Lalicia Roman (b) (4)	26 Aug 2020 19:56:33
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:38:02
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'Yes (Y)'	Lalicia Roman (b) (4)	26 Aug 2020 19:56:33
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:38:04
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered empty.	Lalicia Roman (b) (4)	26 Aug 2020 19:56:33
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:38:07
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'No (N)'	Lalicia Roman (b) (4)	26 Aug 2020 19:56:33
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 19:56:33

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 19:56:33

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 19:56:33

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: FLUOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: PROZAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 15:07:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 15:07:59
Data point term sent to Coder Coding entries removed.	System Emily Dougherty (b) (4)	19 Nov 2020 15:06:54 19 Nov 2020 15:06:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:39:28
User signature succeeded.	Judith Martin (b) (4) (b) (4)	09 Sep 2020 18:08:40
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: FLUOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: PROZAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 07:38:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 07:38:42
Data point term sent to Coder User entered 'Prozac'	System Lalicia Roman (b) (4) (b) (4)	26 Aug 2020 19:57:54 26 Aug 2020 19:57:33

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:39:31
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'No (N)'	Lalicia Roman (b) (4)	26 Aug 2020 19:57:33
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:34:51
User closed query 'source states "mild depression" . please confirm ' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 16:34:48
Query 'source states "mild depression" . please confirm ' answered with 'confirmed and updated to mild depression' (Site from CRA).	Emily Dougherty (b) (4)	19 Nov 2020 15:06:44
Signature has been broken.	(b) (4)	
	Emily Dougherty (b) (4)	19 Nov 2020 15:06:31
User entered 'MILD depression' reason for change: Data Entry Error	(b) (4)	
	Emily Dougherty (b) (4)	19 Nov 2020 15:06:31
User opened query 'source states "mild depression" . please confirm ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 20:39:53
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'mild anxiety'	Lalicia Roman (b) (4)	26 Aug 2020 19:57:33
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:40:00
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered '20'	Lalicia Roman (b) (4)	26 Aug 2020 19:57:33
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:40:03
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'mg (mg)'	Lalicia Roman (b) (4)	26 Aug 2020 19:57:33
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:40:05
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered empty.	Lalicia Roman (b) (4)	26 Aug 2020 19:57:33
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:40:07
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'once daily (QD)'	Lalicia Roman (b) (4)	26 Aug 2020 19:57:33
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:40:12
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered empty.	Lalicia Roman (b) (4)	26 Aug 2020 19:57:33
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:40:13
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'Oral (ORAL)'	Lalicia Roman (b) (4)	26 Aug 2020 19:57:33
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:40:15
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered empty.	Lalicia Roman (b) (4)	26 Aug 2020 19:57:33
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:40:17
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'UN UNK 2005'	Lalicia Roman (b) (4)	26 Aug 2020 19:57:33
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:40:20
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered '0'	Lalicia Roman (b) (4)	26 Aug 2020 19:57:33
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:40:23
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'Yes (Y)'	Lalicia Roman (b) (4)	26 Aug 2020 19:57:33
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:40:28
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered empty.	Lalicia Roman (b) (4)	26 Aug 2020 19:57:33
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:40:30
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'No (N)'	Lalicia Roman (b) (4)	26 Aug 2020 19:57:33
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 19:57:33

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 19:57:33

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 19:57:33

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:40:44
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: BISPHOSPHONATES, PRODUCT: IBANDRONATE SODIUM, PRODUCTSYNONYM: BONIVA - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Aug 2020 18:12:32
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	27 Aug 2020 18:12:32
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\202003.		
Data point term sent to Coder	System	26 Aug 2020 19:58:58
User entered 'Boniva'	Lalicia Roman (b) (4)	26 Aug 2020 19:58:28
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:40:46
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'No (N)'	Lalicia Roman (b) (4)	26 Aug 2020 19:58:28
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:40:49
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'mild osteoporosis'	Lalicia Roman (b) (4)	26 Aug 2020 19:58:28
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:40:51
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'unknown'	Lalicia Roman (b) (4)	26 Aug 2020 19:58:28
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:40:53
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'mg (mg)'	Lalicia Roman (b) (4)	26 Aug 2020 19:58:28
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:40:55
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered empty.	Lalicia Roman (b) (4)	26 Aug 2020 19:58:28
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:40:59
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'every month (QM)'	Lalicia Roman (b) (4)	26 Aug 2020 19:58:28
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:41:06
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered empty.	Lalicia Roman (b) (4)	26 Aug 2020 19:58:28
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:41:10
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'Oral (ORAL)'	Lalicia Roman (b) (4)	26 Aug 2020 19:58:28
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:41:12
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered empty.	Lalicia Roman (b) (4)	26 Aug 2020 19:58:28
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:41:14
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'UN UNK 2017'	Lalicia Roman (b) (4)	26 Aug 2020 19:58:28
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:41:16
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered '0'	Lalicia Roman (b) (4)	26 Aug 2020 19:58:28
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:41:18
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'Yes (Y)'	Lalicia Roman (b) (4)	26 Aug 2020 19:58:28
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:41:19
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered empty.	Lalicia Roman (b) (4)	26 Aug 2020 19:58:28
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:41:21
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'No (N)'	Lalicia Roman (b) (4)	26 Aug 2020 19:58:28
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 19:58:28

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 19:58:28

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '802 (802)'	System	26 Aug 2020 19:58:28

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:41:34
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Sep 2020 07:48:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Sep 2020 07:48:36
Data point term sent to Coder	System	08 Sep 2020 12:41:29
User closed query 'CDM-Coding: The trade name pepcid can be referenced with multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with the drug name. ' (Site from System).	System	08 Sep 2020 12:41:14
Query 'CDM-Coding: The trade name pepcid can be referenced with multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with the drug name. ' answered with 'updated' (Site from System).	(b) (4), (b) (6)	08 Sep 2020 12:41:14
Data point term sent to Coder	System	08 Sep 2020 12:39:27
User entered 'PEPCID-famotidine' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 12:38:55
User opened query 'CDM-Coding: The trade name pepcid can be referenced with multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with the drug name. ' (Site from System).	Coder Import (b) (4)	08 Sep 2020 02:51:37
Data point term sent to Coder	System	26 Aug 2020 20:00:02
User entered 'Pepcid'	Lalicia Roman (b) (4)	26 Aug 2020 19:59:13

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:41:36
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'No (N)'	Lalicia Roman (b) (4)	26 Aug 2020 19:59:13
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:41:42
User closed query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 02:24:11
Query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' answered with 'Acid Indigestion has been added Med History ' (Site from DM).	Emily Carney (b) (4)	20 Oct 2020 19:40:45
User opened query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 13:38:18
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
User entered 'acid indigestion'	Lalicia Roman (b) (4)	26 Aug 2020 19:59:13

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:41:49
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'unknown'	Lalicia Roman (b) (4)	26 Aug 2020 19:59:13
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:41:53
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'mg (mg)'	Lalicia Roman (b) (4)	26 Aug 2020 19:59:13
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:41:55
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered empty.	Lalicia Roman (b) (4)	26 Aug 2020 19:59:13
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:41:58
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'as needed (PRN)'	Lalicia Roman (b) (4)	26 Aug 2020 19:59:13
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:42:00
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered empty.	Lalicia Roman (b) (4)	26 Aug 2020 19:59:13
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:42:01
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'Oral (ORAL)'	Lalicia Roman (b) (4)	26 Aug 2020 19:59:13
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:42:05
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered empty.	Lalicia Roman (b) (4)	26 Aug 2020 19:59:13
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:42:06
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'UN UNK 2000'	Lalicia Roman (b) (4)	26 Aug 2020 19:59:13
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:42:09
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered '0'	Lalicia Roman (b) (4)	26 Aug 2020 19:59:13
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:42:10
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'Yes (Y)'	Lalicia Roman (b) (4)	26 Aug 2020 19:59:13
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:42:12
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered empty.	Lalicia Roman (b) (4)	26 Aug 2020 19:59:13
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:42:13
User signature succeeded.	Judith Martin (b) (4)	09 Sep 2020 18:08:40
	(b) (4)	
User entered 'No (N)'	Lalicia Roman (b) (4)	26 Aug 2020 19:59:13
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 19:59:13

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 19:59:13

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 19:59:13

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:43:40
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)	21 Oct 2020 12:45:31
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 12:45:31
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 12:44:20
User entered 'Influenza vaccine'	Emily Carney (b) (4)	21 Oct 2020 12:44:05
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:43:41
User entered 'Yes (Y)'	Emily Carney (b) (4)	21 Oct 2020 12:44:05
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:43:49
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 20:43:46
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:43:43
User entered 'Prevent flu'	Emily Carney (b) (4)	21 Oct 2020 12:44:05
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:43:47
User entered '1'	Emily Carney (b) (4)	21 Oct 2020 12:44:05
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:43:50
User entered 'Other (OTHER)'	Emily Carney (b) (4)	21 Oct 2020 12:44:05
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:43:52
User entered 'Injection'	Emily Carney (b) (4)	21 Oct 2020 12:44:05
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:43:53
User entered 'other (OTHER)'	Emily Carney (b) (4)	21 Oct 2020 12:44:05
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:43:55
User entered 'Yearly'	Emily Carney (b) (4)	21 Oct 2020 12:44:05
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:43:56
User entered 'Intramuscular (INTRAMUSCULAR)'	Emily Carney (b) (4)	21 Oct 2020 12:44:05
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:43:58
User entered empty.	Emily Carney (b) (4)	21 Oct 2020 12:44:05
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:44:00
User entered '20 Oct 2020'	Emily Carney (b) (4)	21 Oct 2020 12:44:05
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:44:01
User entered '0'	Emily Carney (b) (4)	21 Oct 2020 12:44:05
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:44:05
User entered 'No (N)'	Emily Carney (b) (4)	21 Oct 2020 12:44:05
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:44:04
User entered '20 Oct 2020'	Emily Carney (b) (4)	21 Oct 2020 12:44:05
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:44:07
User entered 'No (N)'	Emily Carney (b) (4)	21 Oct 2020 12:44:05
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 12:44:05

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 12:44:05

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 12:44:05

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

[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 17:34:07
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 17:34:07
Data point term sent to Coder	System	24 Nov 2020 16:23:30
User entered 'Dexamethasone'	Melissa Andrasko (b) (4)	24 Nov 2020 16:22:29

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melissa Andrasko (b) (4)	24 Nov 2020 16:22:29

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

[Indication](#)

Audit	User	Time (GMT)
User entered 'COVID 19 PNA'	Melissa Andrasko (b) (4)	24 Nov 2020 16:22:29

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '6'	Melissa Andrasko (b) (4)	24 Nov 2020 16:22:29

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Melissa Andrasko (b) (4)	24 Nov 2020 16:22:29

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Melissa Andrasko (b) (4)	24 Nov 2020 16:22:29

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Melissa Andrasko (b) (4)	24 Nov 2020 16:22:29

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Andrasko (b) (4)	24 Nov 2020 16:22:29

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Melissa Andrasko (b) (4)	24 Nov 2020 16:22:29

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Melissa Andrasko (b) (4)	24 Nov 2020 16:22:29

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '22 Nov 2020'	Melissa Andrasko (b) (4)	24 Nov 2020 16:22:29

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melissa Andrasko (b) (4)	24 Nov 2020 16:22:29

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melissa Andrasko (b) (4)	24 Nov 2020 16:22:29

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Melissa Andrasko (b) (4)	24 Nov 2020 16:22:29

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melissa Andrasko (b) (4)	24 Nov 2020 16:22:29

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 16:22:29

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 16:22:29

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Nov 2020 16:22:29

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:14
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 21:28:03
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 21:28:03
Data point term sent to Coder	System	24 Nov 2020 21:27:21
User entered 'acetaminophen'	Jennifer Nagg (b) (4)	24 Nov 2020 21:27:01
	(b) (4)	

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:16
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:27:01

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:17
User entered 'covid 19'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:27:01

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:19
User entered '325'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:27:01

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:29
User entered 'mg (mg)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:27:01

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:31
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:27:01

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:34
User entered 'as needed (PRN)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:27:01

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:36
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:27:01

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:37
User entered 'Oral (ORAL)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:27:01

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:41
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:27:01

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:43
User entered '13 Nov 2020'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:27:01

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:45
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:27:01

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:46
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:27:01

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:48
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:27:01

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:50
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:27:01

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 21:27:01

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 21:27:01

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 21:27:01

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:20:44

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:59:00
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:29:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:29:04
Data point term sent to Coder	System	24 Nov 2020 21:28:23
User entered 'aspirin'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:28:06

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:20:44

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:59:02
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:28:06

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:20:44

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:59:04
User entered 'DVT prevention'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:28:06

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:20:44

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:59:05
User entered '81'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:28:06

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:20:44

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:59:07
User entered 'mg (mg)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:28:06

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:20:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:59:09
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:28:06

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:20:44

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:59:11
User entered 'once daily (QD)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:28:06

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:20:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:59:13
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:28:06

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:20:44

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:59:15
User entered 'Oral (ORAL)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:28:06

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:20:44

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:59:16
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:28:06

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:59:18
User entered '14 Nov 2020'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:28:06

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:59:20
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:28:06

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:20:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:59:21
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:28:06

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:20:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:59:23
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:28:06

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:20:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:59:24
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:28:06

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:20:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 21:28:06

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 21:28:06

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Nov 2020 21:28:06

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:20:44

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:55:30
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:31:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:31:41
Data point term sent to Coder	System	24 Nov 2020 21:30:31
User entered 'ibuprofen'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:29:40

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:20:44

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:55:31
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:29:40

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:20:44

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:55:33
User entered 'pain'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:29:40

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:20:44

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:55:34
User entered '400'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:29:40

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:20:44

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:55:38
User entered 'mg (mg)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:29:40

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:20:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:55:42
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:29:40

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:20:44

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:55:44
User entered 'as needed (PRN)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:29:40

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:20:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:55:45
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:29:40

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:20:44

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:55:47
User entered 'Oral (ORAL)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:29:40

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:20:44

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:55:48
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:29:40

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:55:50
User entered '17 Nov 2020'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:29:40

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:55:51
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:29:40

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:20:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:55:53
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:29:40

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:20:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:55:55
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:29:40

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:20:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:55:56
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:29:40

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:20:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 21:29:40

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 21:29:40

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 21:29:40

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:20:44

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:56:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:31:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:31:57
Data point term sent to Coder	System	24 Nov 2020 21:31:32
User entered 'vitamin D'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:30:59

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:20:44

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:56:04
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:30:59

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:20:44

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:56:07
User entered 'covid 19'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:30:59

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:20:44

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:56:13
User entered '1000'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:30:59

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:20:44

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:56:16
User entered 'IU (IU)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:30:59

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:20:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:56:17
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:30:59

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:20:44

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:56:19
User entered 'once daily (QD)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:30:59

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:20:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:56:20
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:30:59

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:20:44

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:56:22
User entered 'Oral (ORAL)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:30:59

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:20:44

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:56:23
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:30:59

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:56:25
User entered '14 Nov 2020'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:30:59

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:56:26
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:30:59

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:20:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:56:28
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:30:59

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:20:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:56:29
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:30:59

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:20:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:56:31
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 21:30:59

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:20:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 21:30:59

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 21:30:59

US3802046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Nov 2020 21:30:59

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'USA-US098-2020-MRNA-1273-P301000005'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:06:33
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 01:32:59
Un-reviewed for Safety.	System	23 Nov 2020 19:45:16
DataPoint Un-verified.	System	23 Nov 2020 19:45:16
User entered 'Yes (Y)'	System	23 Nov 2020 19:45:16
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'No (N)'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'No (N)'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'No (N)'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:06:33
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 01:33:00
Un-reviewed for Safety.	System	23 Nov 2020 19:45:16
DataPoint Un-verified.	System	23 Nov 2020 19:45:16
User entered 'Yes (Y)'	System	23 Nov 2020 19:45:16
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'No (N)'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'No (N)'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'No (N)'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'No (N)'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'Judith'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'Martin'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered '3420 Fifth Ave'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'Pittsburgh'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'PA'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered '15213'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:06:33
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
User entered 'US'	System	16 Nov 2020 20:40:06

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Nov 2020 19:06:49
User entered '1'	System	16 Nov 2020 20:40:06

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'USA-US098-2020-MRNA-1273-P301000005'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:06:33
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 01:32:59
Un-reviewed for Safety.	System	23 Nov 2020 19:45:16
DataPoint Un-verified.	System	23 Nov 2020 19:45:16
User entered 'Yes (Y)'	System	23 Nov 2020 19:45:16
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'No (N)'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'No (N)'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'No (N)'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:06:33
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 01:33:00
Un-reviewed for Safety.	System	23 Nov 2020 19:45:16
DataPoint Un-verified.	System	23 Nov 2020 19:45:16
User entered 'Yes (Y)'	System	23 Nov 2020 19:45:16
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'No (N)'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'No (N)'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'No (N)'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'No (N)'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'Judith'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'Martin'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered '3420 Fifth Ave'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'Pittsburgh'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'PA'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered '15213'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:06:33
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
User entered 'US'	System	16 Nov 2020 20:40:06

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Nov 2020 19:06:49
User entered '1'	System	16 Nov 2020 20:40:06

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:20:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
User entered '16/Nov/2020 20:40'	System	16 Nov 2020 20:40:06

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:20:44

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)	24 Nov 2020 19:06:33
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
User entered '1'	(b) (4), (b) (6)	16 Nov 2020 20:40:06

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'USA-US098-2020-MRNA-1273-P301000005'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:06:33
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 01:32:59
Un-reviewed for Safety.	System	23 Nov 2020 19:45:16
DataPoint Un-verified.	System	23 Nov 2020 19:45:16
User entered 'Yes (Y)'	System	23 Nov 2020 19:45:16
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'No (N)'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'No (N)'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'No (N)'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:06:33
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 01:33:00
Un-reviewed for Safety.	System	23 Nov 2020 19:45:16
DataPoint Un-verified.	System	23 Nov 2020 19:45:16
User entered 'Yes (Y)'	System	23 Nov 2020 19:45:16
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'No (N)'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'No (N)'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'No (N)'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'No (N)'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'Judith'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'Martin'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered '3420 Fifth Ave'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'Pittsburgh'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered 'PA'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:39:55
User entered '15213'	System	16 Nov 2020 20:39:33

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:06:33
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:29:30
User entered 'US'	System	16 Nov 2020 20:40:06

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Nov 2020 19:06:49
User entered '1'	System	16 Nov 2020 20:40:06

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:20:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '24/Nov/2020 14:06'	System	24 Nov 2020 19:06:49

US3802046

Folder: SAE USA-US098-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:20:44

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)	24 Nov 2020 19:06:49