

US3802225 (Prod: UPMC University Center)

Generated By: (b) (6)

Generated On: 26 Nov 2020 11:22:16

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US3802225

Form: Participant Creation

Data signed: (b) (4) 19 Sep 2020 11:08:18

Generated On: 26 Nov 2020 11:22:16

[Participant ID](#)

US3802225

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

US3802225

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Sep 2020 11:08:18

Generated On: 26 Nov 2020 11:22:16

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

US3802225

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Sep 2020 11:08:18

Generated On: 26 Nov 2020 11:22:16

Date of Birth (MMM yyyy)	(b) (6) 2001
Age	19
Age Units	YEARS
Age (Derived)	19
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	False
Black	False
Asian	True
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

US3802225

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Sep 2020 11:08:18

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Date of Informed Consent (dd MMM yyyy)	11 SEP 2020
Month and Year of Informed Consent (derived)	SEP 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) 19 Sep 2020 11:08:18

Generated On: 26 Nov 2020 11:22:16

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 02 Oct 2020 15:26:43

Generated On: 26 Nov 2020 11:22:16

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 02 Oct 2020 15:26:43

Generated On: 26 Nov 2020 11:22:16

Condition	INTERMITTENT DIZZINESS
Start date (dd MMM yyyy)	10 SEP 2020
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)	SEP 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	11 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	14:16 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 14:16
Height (<i>xxx.x</i>)	71.5 in
Weight (<i>xxx.x</i>)	164 lb
BMI (<i>xxx.x</i>)	22.60173 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	97.6 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>)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Sep 2020 11:08:18

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Sep 2020 11:08:18

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Sep 2020 11:08:18

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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)	True
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)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Sep 2020 11:08:18

Generated On: 26 Nov 2020 11:22:16

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	11 SEP 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

Data signed: (b) (4) 19 Sep 2020 11:08:18

Generated On: 26 Nov 2020 11:22:16

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

What was the participant's randomization number? 113473

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) 19 Sep 2020 11:08:18

Generated On: 26 Nov 2020 11:22:16

Height	71.5 in
Weight	164 lb

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Sep 2020 11:08:18

Generated On: 26 Nov 2020 11:22:16

Height	71.5 in
Weight	164 lb
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	14:16 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 14:16
Temperature (xxx.x)	97.6 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)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Sep 2020 11:08:18

Generated On: 26 Nov 2020 11:22:16

Height	71.5 in
Weight	164 lb
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	15:18 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 15:18
Temperature (xxx.x)	97.3 F
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	INFRARED
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Sep 2020 11:08:18

Generated On: 26 Nov 2020 11:22:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 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) 19 Sep 2020 11:08:18

Generated On: 26 Nov 2020 11:22:16

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 11 SEP 2020

What was the treatment time? (00:00-23:59) 14:47 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 14:47

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) 19 Sep 2020 11:08:18

Generated On: 26 Nov 2020 11:22:16

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 SEP 2020

Collection time (00:00-23:59)

14:42 (24 HR)

Collection date and time (derived)

11 SEP 2020 14:42

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Sep 2020 11:08:18

Generated On: 26 Nov 2020 11:22:16

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:38	11 SEP 2020 14:38
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Sep 2020 11:08:18

Generated On: 26 Nov 2020 11:22:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 15:19

PC Open Date & Time

11 SEP 2020 15:07

PC Close Date & Time

11 SEP 2020 17:37

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:22:16

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 ☒

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

Yes ☐

No ☒

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

PC Time Stamp 11 SEP 2020 20:44

PC Open Date & Time 11 SEP 2020 18:32

PC Close Date & Time 12 SEP 2020 11:59

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 21:33

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:22:16

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

13 SEP 2020 20:07

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:22:16

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 20:56

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:22:16

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 21:02

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:22:16

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 ☒

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

Yes ☐

No ☒

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

PC Time Stamp 17 SEP 2020 10:04

PC Open Date & Time 16 SEP 2020 12:00

PC Close Date & Time 17 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐
No ☐

Please record your **TEMPERATURE in °F**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 17 SEP 2020 12:00

PC Close Date & Time 18 SEP 2020 11:59

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 15:20

PC Open Date & Time

11 SEP 2020 15:07

PC Close Date & Time

11 SEP 2020 17:37

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 20:45

PC Open Date & Time

11 SEP 2020 18:32

PC Close Date & Time

12 SEP 2020 11:59

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:22:16

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

12 SEP 2020 21:34

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:22:16

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

13 SEP 2020 20:07

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 20:56

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 21:02

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 10:04

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:16

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 15:21
PC Open Date & Time	11 SEP 2020 15:07
PC Close Date & Time	11 SEP 2020 17:37

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:16

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 20:45
PC Open Date & Time	11 SEP 2020 18:32
PC Close Date & Time	12 SEP 2020 11:59

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:16

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 ☒

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:16

Yes ☐	
PC Time stamp	12 SEP 2020 21:34
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:16

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 ☒

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:16

Yes ☐	
PC Time stamp	13 SEP 2020 20:08
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:16

Yes ☐	
PC Time stamp	14 SEP 2020 20:57
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:16

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 ☒

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:16

Yes ☐	
PC Time stamp	15 SEP 2020 21:02
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:16

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 ☒

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:16

Yes ☐	
PC Time stamp	17 SEP 2020 10:05
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:22:16

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

US3802225

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Sep 2020 11:08:18

Generated On: 26 Nov 2020 11:22:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3802225

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Sep 2020 11:08:18

Generated On: 26 Nov 2020 11:22:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802225

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 25 Sep 2020 16:24:18

Generated On: 26 Nov 2020 11:22:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3802225

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 25 Sep 2020 16:24:18

Generated On: 26 Nov 2020 11:22:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802225

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 02 Oct 2020 15:26:43

Generated On: 26 Nov 2020 11:22:16

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3802225

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 02 Oct 2020 15:26:43

Generated On: 26 Nov 2020 11:22:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802225

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:22:16

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	VISIT2
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US3802225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Oct 2020 15:26:43

Generated On: 26 Nov 2020 11:22:16

Timepoint	Pre-Dose ☒
	Post-Dose ☐
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	

US3802225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Oct 2020 15:26:43

Generated On: 26 Nov 2020 11:22:16

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

US3802225

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Oct 2020 15:26:43

Generated On: 26 Nov 2020 11:22:16

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.

US3802225

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 02 Oct 2020 15:26:43

Generated On: 26 Nov 2020 11:22:16

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?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3802225

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Oct 2020 15:26:43

Generated On: 26 Nov 2020 11:22:16

Was the sample collected? Yes ☐
No ☐

Collection date (dd MMM yyyy) _____

Collection time (00:00-23:59) _____

Collection date and time (derived) _____

US3802225

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 02 Oct 2020 15:26:43

Generated On: 26 Nov 2020 11:22:16

Collection date (dd MMM yyyy)			
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1			
Nasopharyngeal Swab 2			

US3802225

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802225

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:16

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

US3802225

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802225

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:16

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

US3802225

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802225

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:16

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

US3802225

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802225

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:22:16

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	23 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3802225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	23 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	14:02 (24 HR)
Vital Signs Date and Time (derived)	23 NOV 2020 14:02
Temperature (<i>xxx.x</i>)	99.2 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	INFRARED
Pulse (<i>xxx</i>)	86 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3802225

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:22:16

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.

US3802225

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:22:16

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	23 NOV 2020
Collection time (<i>00:00-23:59</i>)	14:12 (24 HR)
Collection date and time (derived)	23 NOV 2020 14:12

US3802225

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 NOV 2020 00:49:17
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3802225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 00:09:50

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2020 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

19 NOV 2020 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2020 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2020 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

17 DEC 2020 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

24 DEC 2020 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

31 DEC 2020 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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11 FEB 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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14 FEB 2021 00:01

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18 FEB 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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28 FEB 2021 00:01

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04 MAR 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 MAR 2021 00:01

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11 MAR 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 AUG 2021 00:01

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12 AUG 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 AUG 2021 00:01

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02 SEP 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 JAN 2022 00:01

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20 JAN 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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23 JAN 2022 00:01

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27 JAN 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT	DAY 523
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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°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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

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US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

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US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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24 MAR 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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31 MAR 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 APR 2022 00:01

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07 APR 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

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US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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°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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

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25 AUG 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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28 AUG 2022 00:01

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01 SEP 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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04 SEP 2022 00:01

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08 SEP 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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11 SEP 2022 00:01

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15 SEP 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 SEP 2022 00:01

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22 SEP 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 ☐

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2022 23:59

US3802225

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:16

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

US3802225

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:16

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:22:16

Date of Contact	18 SEP 2020
Time of Contact	15:00
Date and Time of Contact (derived)	18 SEP 2020 15:00
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☒
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐
	No ☒

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Sep 2020 11:08:18

Generated On: 26 Nov 2020 11:22:16

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	☐

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Sep 2020 11:08:18

Generated On: 26 Nov 2020 11:22:16

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	18 SEP 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature		
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	☐
v6.020 DTW (1102)	297 of 1179	

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Sep 2020 11:08:18

Generated On: 26 Nov 2020 11:22:16

	Not Done	☐
Fatigue	None	☒
	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	☐

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Sep 2020 11:08:18

Generated On: 26 Nov 2020 11:22:16

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
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 ☐

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 19 Sep 2020 11:08:18

Generated On: 26 Nov 2020 11:22:16

Date of Visit	11 SEP 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ☒ No ☐
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ☒ No ☐
Date of Test	11 SEP 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

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

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:

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

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 _____

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

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

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:22:16

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

US3802225

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 19 Sep 2020 11:08:18

Generated On: 26 Nov 2020 11:22:16

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

US3802225

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 19 Sep 2020 11:08:18

Generated On: 26 Nov 2020 11:22:16

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 _____

US3802225

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

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)	

US3802225

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Sep 2020 11:08:18

Generated On: 26 Nov 2020 11:22:16

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.

US3802225

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 19 Sep 2020 11:08:18

Generated On: 26 Nov 2020 11:22:16

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

No ☐

NA (COVID-19 Negative) ☐

Date of Collection _____

US3802225

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 19 Sep 2020 11:08:18

Generated On: 26 Nov 2020 11:22:16

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 _____

US3802225

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

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)	

US3802225

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Sep 2020 11:08:18

Generated On: 26 Nov 2020 11:22:16

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.

US3802225

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 19 Sep 2020 11:08:18

Generated On: 26 Nov 2020 11:22:16

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

US3802225

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 02 Oct 2020 15:26:43

Generated On: 26 Nov 2020 11:22:16

Did the participant experience any adverse events?

Yes ☐

No ☒

If Yes, enter details on the Adverse Events form.

US3802225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:22:16

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

Yes ☒

No ☐

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

US3802225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:16

Name of Medication	INFLUENZA VACCINE
Prophylaxis	Yes ☒ No ☐
Indication	PREVENT INFLUENZA INFECTION
Dose per administration	0.5
Dose unit	mg ☐ ug ☐ mL ☒ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3802225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:16

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

US3802225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Sep 2020 11:08:18

Generated On: 26 Nov 2020 11:22:16

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3802225

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 19 Sep 2020 11:08:18

Generated On: 26 Nov 2020 11:22:16

Date of dosing discontinuation (dd MMM yyyy) 15 SEP 2020

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

US3802225

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 19 Sep 2020 11:08:18

Generated On: 26 Nov 2020 11:22:16

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	☐

Audit

US3802225 (Prod: UPMC University Center)

US3802225

Form: Participant Creation

Generated On: 26 Nov 2020 11:22:16

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'US3802225'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 18:15:16

US3802225

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:22:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:25:52
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4)	11 Sep 2020 18:16:15

US3802225

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:25:52
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '11 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 18:15:21

US3802225

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:25:52
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Clinic (Clinic)'	(b) (4) Jennifer Nagg (b) (4)	11 Sep 2020 18:16:15

US3802225

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:22:16

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	11 Sep 2020 18:16:15

US3802225

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:26:44
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered (b) (6) 2001'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 18:15:24

US3802225

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:22:16

[Age](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:26:44
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '19'	Matthew Lee (b) (4)	11 Sep 2020 19:09:05

US3802225

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:22:16

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	11 Sep 2020 19:09:05

US3802225

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:22:16

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '19'	System	11 Sep 2020 18:16:31

US3802225

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:22:16

[Sex](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:26:44
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Male (M)'	Matthew Lee (b) (4)	11 Sep 2020 19:09:05

US3802225

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:22:16

[Ethnicity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:26:44
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:09:05

US3802225

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:22:16

[White](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:26:44
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '0'	Matthew Lee (b) (4)	11 Sep 2020 19:09:05

US3802225

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:22:16

[Black](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:26:44
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '0'	Matthew Lee (b) (4)	11 Sep 2020 19:09:05

US3802225

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:22:16

[Asian](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:26:44
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '1'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:09:05

US3802225

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:22:16

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:26:44
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '0'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:09:05

US3802225

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:22:16

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:26:44
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '0'	Matthew Lee (b) (4)	11 Sep 2020 19:09:05

US3802225

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:22:16

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:26:44
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '0'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:09:05

US3802225

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:22:16

[If race is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:26:44
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered empty.	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:09:05

US3802225

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:22:16

[Unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:26:44
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '0'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:09:05

US3802225

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:22:16

[Not reported](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:26:44
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '0'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:09:05

US3802225

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:27:11
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '11 Sep 2020'	(b) (4) Jennifer Nagg (b) (4)	11 Sep 2020 18:16:31

US3802225

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	11 Sep 2020 18:16:31

US3802225

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
User entered '2020'	System	11 Sep 2020 18:16:31

US3802225

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:22:16

[Protocol Version](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:27:11
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Amendment 3 (3)'	(b) (4) Jennifer Nagg (b) (4)	11 Sep 2020 18:16:31

US3802225

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:27:11
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4)	11 Sep 2020 18:16:31

US3802225

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:27:11
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	11 Sep 2020 18:16:31

US3802225

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:22:16

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:27:11
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	11 Sep 2020 18:16:31

US3802225

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:22:16

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:27:11
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'No (N)'	(b) (4) Jennifer Nagg (b) (4)	11 Sep 2020 18:16:31

US3802225

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:22:16

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:27:11
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 18:15:21

US3802225

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:22:16

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 18:16:37

US3802225

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:27:50
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4)	11 Sep 2020 18:16:37

US3802225

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:22:16

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:28:39
User signature succeeded.	Judith Martin (b) (4)	02 Oct 2020 15:26:43
Signature has been broken.	(b) (4) Melissa Andrasko (b) (4)	25 Sep 2020 18:51:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Andrasko (b) (4)	25 Sep 2020 18:51:00
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'No (N)'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:10:24

US3802225

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:22:16

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:31:15
User signature succeeded.	Judith Martin (b) (4)	02 Oct 2020 15:26:43
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Dizziness, LLT: Dizziness - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 18:53:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 18:53:50
Data point term sent to Coder	System	25 Sep 2020 18:53:00
User entered 'Intermittent dizziness'	Melissa Andrasko (b) (4)	25 Sep 2020 18:52:03

US3802225

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:31:15
User signature succeeded.	Judith Martin (b) (4)	02 Oct 2020 15:26:43
User entered '10 Sep 2020'	(b) (4) Melissa Andrasko (b) (4)	25 Sep 2020 18:52:03

US3802225

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:22:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:31:15
User signature succeeded.	Judith Martin (b) (4)	02 Oct 2020 15:26:43
User entered '0'	(b) (4) Melissa Andrasko (b) (4)	25 Sep 2020 18:52:03

US3802225

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:22:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:31:15
User signature succeeded.	Judith Martin (b) (4)	02 Oct 2020 15:26:43
User entered 'Yes (Y)'	(b) (4) Melissa Andrasko (b) (4)	25 Sep 2020 18:52:03

US3802225

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:31:15
User signature succeeded.	Judith Martin (b) (4)	02 Oct 2020 15:26:43
User entered empty.	(b) (4) Melissa Andrasko (b) (4)	25 Sep 2020 18:52:03

US3802225

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:22:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:31:15
User signature succeeded.	Judith Martin (b) (4)	02 Oct 2020 15:26:43
User entered '0'	(b) (4) Melissa Andrasko (b) (4)	25 Sep 2020 18:52:03

US3802225

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	25 Sep 2020 18:52:03

US3802225

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
User entered '2020'	System	25 Sep 2020 18:52:03

US3802225

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 18:52:03

US3802225

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 18:52:03

US3802225

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:31:57
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Yes (Y)'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:11:39

US3802225

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:31:57
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '11 Sep 2020'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:11:39

US3802225

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:31:57
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '14:16'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:11:39

US3802225

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 14:16'	System	11 Sep 2020 19:11:39

US3802225

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:31:57
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '71.5' in	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:11:39
DataPoint set to visible.	(b) (4) System	11 Sep 2020 18:16:37

US3802225

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:31:57
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '164' lb	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:11:39
DataPoint set to visible.	(b) (4) System	11 Sep 2020 18:16:37

US3802225

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '22.60173'	System	11 Sep 2020 19:11:39
DataPoint set to visible.	System	11 Sep 2020 18:16:37

US3802225

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	11 Sep 2020 19:11:39
DataPoint set to visible.	System	11 Sep 2020 18:16:37

US3802225

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:31:57
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '97.6' F	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:11:39

US3802225

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:31:57
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Other (Other)'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:11:39

US3802225

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:31:57
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Infrared'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:11:39

US3802225

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:31:57
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '72'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:11:39

US3802225

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Sep 2020 19:11:39

US3802225

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:31:57
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '16'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:11:39

US3802225

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Sep 2020 19:11:39

US3802225

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:31:57
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '130'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:11:39

US3802225

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 19:11:39

US3802225

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:31:57
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '84'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:11:39

US3802225

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 19:11:39

US3802225

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:22:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:34:02
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4)	11 Sep 2020 18:16:48

US3802225

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:34:02
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '11 Sep 2020'	(b) (4) Jennifer Nagg (b) (4)	11 Sep 2020 18:16:48

US3802225

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:34:55
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'No (N)'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:12:14

US3802225

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:34:55
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'No (N)'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:12:14

US3802225

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:34:55
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'No (N)'	Matthew Lee (b) (4)	11 Sep 2020 19:12:14

US3802225

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:34:55
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'No (N)'	Matthew Lee (b) (4)	11 Sep 2020 19:12:14

US3802225

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:34:55
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'No (N)'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:12:14

US3802225

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:34:55
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'No (N)'	Matthew Lee (b) (4)	11 Sep 2020 19:12:14

US3802225

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:34:55
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'No (N)'	Matthew Lee (b) (4)	11 Sep 2020 19:12:14

US3802225

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:34:55
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'No (N)'	Matthew Lee (b) (4)	11 Sep 2020 19:12:14

US3802225

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:34:55
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'No (N)'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:12:14

US3802225

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:34:55
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'No (N)'	Matthew Lee (b) (4)	11 Sep 2020 19:12:14

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:34:55
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Yes (Y)'	Matthew Lee (b) (4)	11 Sep 2020 19:12:14

US3802225

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:16

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:34:55
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'No (N)'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:12:14

US3802225

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:16

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:34:55
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered empty.	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:12:14

US3802225

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:16

No Risk Identified

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
	(b) (4)	
User entered '0'	Matthew Lee (b) (4)	11 Sep 2020 19:12:14
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:16

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:34:55
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '0'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:12:14

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:34:55
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '0'	Matthew Lee (b) (4)	11 Sep 2020 19:12:14

US3802225

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:34:55
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '1'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:12:14

US3802225

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:34:55
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '0'	Matthew Lee (b) (4)	11 Sep 2020 19:12:14

US3802225

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:34:55
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '0'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:12:14

US3802225

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:16

Other

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
	(b) (4)	
User entered '0'	Matthew Lee (b) (4)	11 Sep 2020 19:12:14
	(b) (4)	

US3802225

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:16

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:34:55
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered empty.	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:12:14

US3802225

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:22:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:48:02
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4)	11 Sep 2020 18:17:04

US3802225

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:48:02
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '11 Sep 2020'	(b) (4) Jennifer Nagg (b) (4)	11 Sep 2020 18:17:04

US3802225

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:48:02
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Clinic (Clinic)'	Jennifer Nagg (b) (4)	11 Sep 2020 18:17:04

US3802225

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:22:16

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	11 Sep 2020 18:17:04

US3802225

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:48:55
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '11 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 18:19:48

US3802225

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:48:55
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '113473'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 18:19:48

US3802225

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:48:55
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 18:19:48

US3802225

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:48:55
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'No (N)'	Jennifer Nagg (b) (4)	11 Sep 2020 18:17:20

US3802225

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:48:55
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'No (N)'	Jennifer Nagg (b) (4)	11 Sep 2020 18:17:20

US3802225

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:48:55
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'No (N)'	(b) (4) Jennifer Nagg (b) (4)	11 Sep 2020 18:17:20

US3802225

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:48:55
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'No (N)'	(b) (4) Jennifer Nagg (b) (4)	11 Sep 2020 18:17:20

US3802225

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:22:16

[Liver Disease](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:48:55
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'No (N)'	(b) (4) Jennifer Nagg (b) (4)	11 Sep 2020 18:17:20

US3802225

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 06:13:47
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:13:46

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:22:16

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:49:33
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '71.5' in	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:22:16

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:49:35
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '164' lb	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:22:16

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:49:33
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '71.5' in	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:22:16

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:49:35
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '164' lb	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:16

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Matthew Lee (b) (4) (b) (4)	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:49:48
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Yes (Y)'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:49:50
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '11 Sep 2020'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:49:54
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '14:16'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 14:16'	System	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:16

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:49:56
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '97.6' F	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:16

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:49:57
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Other (Other)'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:16

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:49:58
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Infrared'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:50:01
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '72'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:16

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:50:07
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '16'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:50:08
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '130'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:50:10
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '84'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:22:16

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:49:33
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '71.5' in	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:22:16

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:49:35
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '164' lb	(b) (4) Matthew Lee (b) (4) (b) (4)	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:16

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Matthew Lee (b) (4) (b) (4)	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:50:29
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Yes (Y)'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '11 Sep 2020'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:50:31
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '15:18'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 15:18'	System	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:16

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:50:32
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '97.3' F	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:16

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:50:35
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Other (Other)'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:16

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:50:40
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Infrared'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:50:42
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '81'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:16

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:50:44
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '16'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:50:47
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '120'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:50:52
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '82'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 19:30:17

US3802225

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:22:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:51:46
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Yes (Y)'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:12:31

US3802225

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:51:46
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '11 Sep 2020'	Matthew Lee (b) (4)	11 Sep 2020 19:12:31

US3802225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:22:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:52:10
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Yes (Y)'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:07:13

US3802225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:22:16

[If No, reason not given](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:52:10
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered empty.	Matthew Lee (b) (4)	11 Sep 2020 19:07:13

US3802225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:52:10
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered empty.	Matthew Lee (b) (4)	11 Sep 2020 19:07:13

US3802225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:22:16

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 19:07:13

US3802225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:22:16

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:52:10
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '11 Sep 2020'	Matthew Lee (b) (4)	11 Sep 2020 19:07:13

US3802225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:52:10
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '14:47'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:07:13

US3802225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 14:47'	System	11 Sep 2020 19:07:13

US3802225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:52:10
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Left Arm (LEFT ARM)'	Matthew Lee (b) (4)	11 Sep 2020 19:07:13

US3802225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:52:10
User entered 'ONCE'	System	11 Sep 2020 19:07:13

US3802225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 19:07:13

US3802225

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:22:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:52:42
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Yes (Y)'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:13:45

US3802225

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:52:42
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '11 Sep 2020'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:13:45

US3802225

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:52:42
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '14:42'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:13:45

US3802225

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 14:42'	System	11 Sep 2020 19:13:45

US3802225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:52:57
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '11 Sep 2020'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:14:35

US3802225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:22:16

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Matthew Lee (b) (4) (b) (4)	11 Sep 2020 19:14:35

US3802225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:22:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:53:03
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Yes (Y)'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:14:35

US3802225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:53:06
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '14:38'	Matthew Lee (b) (4)	11 Sep 2020 19:14:35

US3802225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 14:38'	System	11 Sep 2020 19:14:35

US3802225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:22:16

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Matthew Lee (b) (4) (b) (4)	11 Sep 2020 19:14:35

US3802225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:22:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:53:24
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'No (N)'	(b) (4) Matthew Lee (b) (4)	11 Sep 2020 19:14:35

US3802225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:53:24
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered empty.	Matthew Lee (b) (4)	11 Sep 2020 19:14:35

US3802225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 19:14:35

US3802225

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:53:43
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Yes (Y)'	Matthew Lee (b) (4)	11 Sep 2020 19:14:41

US3802225

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:22:16

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 19:14:41

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 19:07:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:22:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-11T15:19:14', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '26bf73aa-ca38-4261-8dd4-e6cb9c2bb7c3'	System	11 Sep 2020 19:19:35
User entered 'Yes (Y)'	System	11 Sep 2020 19:19:35

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:22:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-11T15:19:20', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '26bf73aa-ca38-4261-8dd4-e6cb9c2bb7c3'	System	11 Sep 2020 19:19:35
User entered '97.3'	System	11 Sep 2020 19:19:35

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-11T15:19:24', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '26bf73aa-ca38-4261-8dd4-e6cb9c2bb7c3'	System	11 Sep 2020 19:19:35
User entered 'No (N)'	System	11 Sep 2020 19:19:35

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:22:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-11T15:19:31', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '26bf73aa-ca38-4261-8dd4-e6cb9c2bb7c3'	System	11 Sep 2020 19:19:35
User entered '11 Sep 2020 15:19'	System	11 Sep 2020 19:19:35

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:22:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 15:07'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:22:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 17:37'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 19:07:13
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:22:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-11T20:43:45', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '2b53b9db-66b6-4583-9b4a-ac3e66e965a9'	System	12 Sep 2020 00:53:31
User entered 'No (N)'	System	12 Sep 2020 00:53:31

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-11T20:44:26', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '2b53b9db-66b6-4583-9b4a-ac3e66e965a9'	System	12 Sep 2020 00:53:31
User entered 'No (N)'	System	12 Sep 2020 00:53:31

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:22:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-11T20:44:30', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '2b53b9db-66b6-4583-9b4a-ac3e66e965a9'	System	12 Sep 2020 00:53:31
User entered '11 Sep 2020 20:44'	System	12 Sep 2020 00:53:31

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:22:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 18:32'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:22:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 19:07:13
User entered 'Day 2'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:22:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-12T21:33:40', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '7e9e73f8-bfdf-43ab-96a2-1d46362a9c32'	System	13 Sep 2020 01:33:56
User entered 'Yes (Y)'	System	13 Sep 2020 01:33:56

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:22:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-12T21:33:44', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '7e9e73f8-bfdf-43ab-96a2-1d46362a9c32'	System	13 Sep 2020 01:33:56
User entered '97.3'	System	13 Sep 2020 01:33:56

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-12T21:33:52', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '7e9e73f8-bfdf-43ab-96a2-1d46362a9c32'	System	13 Sep 2020 01:33:56
User entered 'No (N)'	System	13 Sep 2020 01:33:56

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:22:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-12T21:33:55', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '7e9e73f8-bfdf-43ab-96a2-1d46362a9c32'	System	13 Sep 2020 01:33:56
User entered '12 Sep 2020 21:33'	System	13 Sep 2020 01:33:56

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:22:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:22:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 19:07:13
User entered 'Day 3'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:22:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-13T20:07:35', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'e8a7244d-0fd8-48fe-92f6-738e1db964e6'	System	14 Sep 2020 00:08:14
User entered 'Yes (Y)'	System	14 Sep 2020 00:08:14

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:22:16

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-13T20:07:40', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'e8a7244d-0fd8-48fe-92f6-738e1db964e6'	System	14 Sep 2020 00:08:14
User entered '97.9'	System	14 Sep 2020 00:08:14

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-13T20:07:42', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'e8a7244d-0fd8-48fe-92f6-738e1db964e6'	System	14 Sep 2020 00:08:14
User entered 'No (N)'	System	14 Sep 2020 00:08:14

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:22:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-13T20:07:44', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'e8a7244d-0fd8-48fe-92f6-738e1db964e6'	System	14 Sep 2020 00:08:14
User entered '13 Sep 2020 20:07'	System	14 Sep 2020 00:08:14

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:22:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:22:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 19:07:13
User entered 'Day 4'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:22:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-14T20:56:25', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'f607dff9-455c-4a5f-b150-80e165171253'	System	15 Sep 2020 00:56:41
User entered 'Yes (Y)'	System	15 Sep 2020 00:56:41

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:22:16

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-14T20:56:29', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'f607dff9-455c-4a5f-b150-80e165171253'	System	15 Sep 2020 00:56:41
User entered '97.0'	System	15 Sep 2020 00:56:41

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-14T20:56:36', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'f607dff9-455c-4a5f-b150-80e165171253'	System	15 Sep 2020 00:56:41
User entered 'No (N)'	System	15 Sep 2020 00:56:41

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:22:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-14T20:56:38', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'f607dff9-455c-4a5f-b150-80e165171253'	System	15 Sep 2020 00:56:41
User entered '14 Sep 2020 20:56'	System	15 Sep 2020 00:56:41

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:22:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:22:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 19:07:13
User entered 'Day 5'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:22:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-15T21:01:40', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '4e7ad284-c2a6-445c-99bf-c6f8953d6d5c'	System	16 Sep 2020 01:02:06
User entered 'Yes (Y)'	System	16 Sep 2020 01:02:06

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:22:16

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-15T21:01:44', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '4e7ad284-c2a6-445c-99bf-c6f8953d6d5c'	System	16 Sep 2020 01:02:06
User entered '97.0'	System	16 Sep 2020 01:02:06

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-15T21:02:00', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '4e7ad284-c2a6-445c-99bf-c6f8953d6d5c'	System	16 Sep 2020 01:02:06
User entered 'No (N)'	System	16 Sep 2020 01:02:06

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:22:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-15T21:02:02', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '4e7ad284-c2a6-445c-99bf-c6f8953d6d5c'	System	16 Sep 2020 01:02:06
User entered '15 Sep 2020 21:02'	System	16 Sep 2020 01:02:06

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:22:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:22:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 19:07:13
User entered 'Day 6'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:22:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-17T10:04:41', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'b2ab52ec-d816-4deb-aad7-7553f7d2a68b'	System	17 Sep 2020 14:04:48
User entered 'No (N)'	System	17 Sep 2020 14:04:48

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-17T10:04:43', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'b2ab52ec-d816-4deb-aad7-7553f7d2a68b'	System	17 Sep 2020 14:04:48
User entered 'No (N)'	System	17 Sep 2020 14:04:48

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:22:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-17T10:04:45', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'b2ab52ec-d816-4deb-aad7-7553f7d2a68b' User entered '17 Sep 2020 10:04'	System	17 Sep 2020 14:04:48
	System	17 Sep 2020 14:04:48

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:22:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:22:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 19:07:13
User entered 'Day 7'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:22:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:22:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 19:07:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:22:16

[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 (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-11T15:20:04', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '31aee7f1-332d-4358-a09a-2b1bc1881871'	System	11 Sep 2020 19:20:44
User entered 'None (1)'	System	11 Sep 2020 19:20:44

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-11T15:20:07', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '31aee7f1-332d-4358-a09a-2b1bc1881871'	System	11 Sep 2020 19:20:44
User entered 'No (N)'	System	11 Sep 2020 19:20:44

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-11T15:20:10', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '31aee7f1-332d-4358-a09a-2b1bc1881871'	System	11 Sep 2020 19:20:44
User entered 'No (N)'	System	11 Sep 2020 19:20:44

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:22:16

[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 (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-11T15:20:35', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '31aee7f1-332d-4358-a09a-2b1bc1881871'	System	11 Sep 2020 19:20:44
User entered 'None (1)'	System	11 Sep 2020 19:20:44

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:22:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-11T15:20:39', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '31aee7f1-332d-4358-a09a-2b1bc1881871'	System	11 Sep 2020 19:20:44
User entered '11 Sep 2020 15:20'	System	11 Sep 2020 19:20:44

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:22:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 15:07'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:22:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 17:37'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 19:07:13
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:22:16

[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 (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-11T20:44:47', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '507dfb79-7511-4707-b9af-d4c265e59cc9'	System	12 Sep 2020 00:53:48
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 00:53:48

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:22:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-11T20:45:06', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '507dfb79-7511-4707-b9af-d4c265e59cc9'	System	12 Sep 2020 00:53:48
User entered 'No (N)'	System	12 Sep 2020 00:53:48

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-11T20:45:15', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '507dfb79-7511-4707-b9af-d4c265e59cc9'	System	12 Sep 2020 00:53:48
User entered 'No (N)'	System	12 Sep 2020 00:53:48

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:22:16

[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 (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-11T20:45:19', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '507dfb79-7511-4707-b9af-d4c265e59cc9'	System	12 Sep 2020 00:53:48
User entered 'None (1)'	System	12 Sep 2020 00:53:48

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:22:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-11T20:45:20', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '507dfb79-7511-4707-b9af-d4c265e59cc9'	System	12 Sep 2020 00:53:48
User entered '11 Sep 2020 20:45'	System	12 Sep 2020 00:53:48

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:22:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 18:32'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:22:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 19:07:13
User entered 'Day 2'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:22:16

[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 (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-12T21:33:58', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '72e5a03e-f764-4c2d-a21c-03512ea016a6'	System	13 Sep 2020 01:34:10
User entered 'None (1)'	System	13 Sep 2020 01:34:10

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-12T21:34:01', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '72e5a03e-f764-4c2d-a21c-03512ea016a6'	System	13 Sep 2020 01:34:10
User entered 'No (N)'	System	13 Sep 2020 01:34:10

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-12T21:34:02', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '72e5a03e-f764-4c2d-a21c-03512ea016a6'	System	13 Sep 2020 01:34:10
User entered 'No (N)'	System	13 Sep 2020 01:34:10

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:22:16

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 (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-12T21:34:04', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '72e5a03e-f764-4c2d-a21c-03512ea016a6'	System	13 Sep 2020 01:34:10
User entered 'None (1)'	System	13 Sep 2020 01:34:10

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:22:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-12T21:34:06', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '72e5a03e-f764-4c2d-a21c-03512ea016a6'	System	13 Sep 2020 01:34:10
User entered '12 Sep 2020 21:34'	System	13 Sep 2020 01:34:10

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:22:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:22:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 19:07:13
User entered 'Day 3'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:22:16

[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 (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-13T20:07:48', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '0be244a6-2c44-4858-ae7-4f6e92b0105a'	System	14 Sep 2020 00:08:17
User entered 'None (1)'	System	14 Sep 2020 00:08:17

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-13T20:07:49', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '0be244a6-2c44-4858-ae7-4f6e92b0105a'	System	14 Sep 2020 00:08:17
User entered 'No (N)'	System	14 Sep 2020 00:08:17

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-13T20:07:52', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '0be244a6-2c44-4858-ae7-4f6e92b0105a'	System	14 Sep 2020 00:08:17
User entered 'No (N)'	System	14 Sep 2020 00:08:17

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:22:16

[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 (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-13T20:07:54', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '0be244a6-2c44-4858-ae7-4f6e92b0105a'	System	14 Sep 2020 00:08:17
User entered 'None (1)'	System	14 Sep 2020 00:08:17

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:22:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-13T20:07:56', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '0be244a6-2c44-4858-ae7-4f6e92b0105a'	System	14 Sep 2020 00:08:17
User entered '13 Sep 2020 20:07'	System	14 Sep 2020 00:08:17

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:22:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:22:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 19:07:13
User entered 'Day 4'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:22:16

[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 (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-14T20:56:41', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'a319e158-bfe2-4dfb-8fa4-99672c63b4e1'	System	15 Sep 2020 00:56:51
User entered 'None (1)'	System	15 Sep 2020 00:56:51

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:22:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-14T20:56:43', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'a319e158-bfe2-4dfb-8fa4-99672c63b4e1'	System	15 Sep 2020 00:56:51
User entered 'No (N)'	System	15 Sep 2020 00:56:51

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-14T20:56:44', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'a319e158-bfe2-4dfb-8fa4-99672c63b4e1'	System	15 Sep 2020 00:56:51
User entered 'No (N)'	System	15 Sep 2020 00:56:51

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:22:16

[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 (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-14T20:56:46', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'a319e158-bfe2-4dfb-8fa4-99672c63b4e1'	System	15 Sep 2020 00:56:51
User entered 'None (1)'	System	15 Sep 2020 00:56:51

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:22:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-14T20:56:47', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'a319e158-bfe2-4dfb-8fa4-99672c63b4e1'	System	15 Sep 2020 00:56:51
User entered '14 Sep 2020 20:56'	System	15 Sep 2020 00:56:51

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:22:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:22:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 19:07:13
User entered 'Day 5'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:22:16

[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 (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-15T21:02:05', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'f1c9610d-4208-4b73-b835-0caaff53faeb'	System	16 Sep 2020 01:02:17
User entered 'None (1)'	System	16 Sep 2020 01:02:17

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-15T21:02:07', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'f1c9610d-4208-4b73-b835-0caaff53faeb'	System	16 Sep 2020 01:02:17
User entered 'No (N)'	System	16 Sep 2020 01:02:17

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-15T21:02:10', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'f1c9610d-4208-4b73-b835-0caaff53faeb'	System	16 Sep 2020 01:02:17
User entered 'No (N)'	System	16 Sep 2020 01:02:17

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:22:16

[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 (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-15T21:02:14', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'f1c9610d-4208-4b73-b835-0caaff53faeb'	System	16 Sep 2020 01:02:17
User entered 'None (1)'	System	16 Sep 2020 01:02:17

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:22:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-15T21:02:16', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'f1c9610d-4208-4b73-b835-0caaff53faeb'	System	16 Sep 2020 01:02:17
User entered '15 Sep 2020 21:02'	System	16 Sep 2020 01:02:17

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:22:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:22:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 19:07:13
User entered 'Day 6'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:22:16

[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 (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-17T10:04:49', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '1c744342-c1c2-4c5b-b934-0e53cc3b5c66'	System	17 Sep 2020 14:05:00
User entered 'None (1)'	System	17 Sep 2020 14:05:00

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:22:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-17T10:04:50', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '1c744342-c1c2-4c5b-b934-0e53cc3b5c66'	System	17 Sep 2020 14:05:00
User entered 'No (N)'	System	17 Sep 2020 14:05:00

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-17T10:04:51', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '1c744342-c1c2-4c5b-b934-0e53cc3b5c66'	System	17 Sep 2020 14:05:00
User entered 'No (N)'	System	17 Sep 2020 14:05:00

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:22:16

[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 (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-17T10:04:53', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '1c744342-c1c2-4c5b-b934-0e53cc3b5c66'	System	17 Sep 2020 14:05:00
User entered 'None (1)'	System	17 Sep 2020 14:05:00

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:22:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-17T10:04:55', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '1c744342-c1c2-4c5b-b934-0e53cc3b5c66'	System	17 Sep 2020 14:05:00
User entered '17 Sep 2020 10:04'	System	17 Sep 2020 14:05:00

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:22:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:22:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 19:07:13
User entered 'Day 7'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:22:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:22:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 19:07:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:16

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-11T15:20:46', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'a8918ae1-be20-4dbb-ba4c-975ab03d72ce'	System	11 Sep 2020 19:21:11
User entered 'None (0)'	System	11 Sep 2020 19:21:11

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:16

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-11T15:20:49', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'a8918ae1-be20-4dbb-ba4c-975ab03d72ce'	System	11 Sep 2020 19:21:11
User entered 'None (0)'	System	11 Sep 2020 19:21:11

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-11T15:20:52', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'a8918ae1-be20-4dbb-ba4c-975ab03d72ce'	System	11 Sep 2020 19:21:11
User entered 'None (0)'	System	11 Sep 2020 19:21:11

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-11T15:20:53', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'a8918ae1-be20-4dbb-ba4c-975ab03d72ce'	System	11 Sep 2020 19:21:11
User entered 'None (0)'	System	11 Sep 2020 19:21:11

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-11T15:20:56', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'a8918ae1-be20-4dbb-ba4c-975ab03d72ce'	System	11 Sep 2020 19:21:11
User entered 'None (0)'	System	11 Sep 2020 19:21:11

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:16

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-11T15:20:58', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'a8918ae1-be20-4dbb-ba4c-975ab03d72ce'	System	11 Sep 2020 19:21:11
User entered 'None (0)'	System	11 Sep 2020 19:21:11

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:16

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 (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-11T15:21:03', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'a8918ae1-be20-4dbb-ba4c-975ab03d72ce'	System	11 Sep 2020 19:21:11
User entered 'No (N)'	System	11 Sep 2020 19:21:11

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:16

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-11T15:21:05', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'a8918ae1-be20-4dbb-ba4c-975ab03d72ce'	System	11 Sep 2020 19:21:11
User entered '11 Sep 2020 15:21'	System	11 Sep 2020 19:21:11

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 15:07'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 17:37'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 19:07:13
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:16

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-11T20:45:23', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '96427f7a-a4b3-4de9-9f7d-42769cf6d009'	System	12 Sep 2020 00:53:51
User entered 'None (0)'	System	12 Sep 2020 00:53:51

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:16

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-11T20:45:25', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '96427f7a-a4b3-4de9-9f7d-42769cf6d009'	System	12 Sep 2020 00:53:51
User entered 'None (0)'	System	12 Sep 2020 00:53:51

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-11T20:45:26', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '96427f7a-a4b3-4de9-9f7d-42769cf6d009'	System	12 Sep 2020 00:53:51
User entered 'None (0)'	System	12 Sep 2020 00:53:51

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-11T20:45:27', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '96427f7a-a4b3-4de9-9f7d-42769cf6d009'	System	12 Sep 2020 00:53:51
User entered 'None (0)'	System	12 Sep 2020 00:53:51

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-11T20:45:29', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '96427f7a-a4b3-4de9-9f7d-42769cf6d009'	System	12 Sep 2020 00:53:51
User entered 'None (0)'	System	12 Sep 2020 00:53:51

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:16

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-11T20:45:30', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '96427f7a-a4b3-4de9-9f7d-42769cf6d009'	System	12 Sep 2020 00:53:51
User entered 'None (0)'	System	12 Sep 2020 00:53:51

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:16

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 (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-11T20:45:32', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '96427f7a-a4b3-4de9-9f7d-42769cf6d009'	System	12 Sep 2020 00:53:51
User entered 'No (N)'	System	12 Sep 2020 00:53:51

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:16

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-11T20:45:33', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '96427f7a-a4b3-4de9-9f7d-42769cf6d009'	System	12 Sep 2020 00:53:51
User entered '11 Sep 2020 20:45'	System	12 Sep 2020 00:53:51

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 18:32'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 19:07:13
User entered 'Day 2'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:16

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-12T21:34:09', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'b07d5d20-813e-4fcc-8ffc-8f2b7f54ffa1'	System	13 Sep 2020 01:34:24
User entered 'None (0)'	System	13 Sep 2020 01:34:24

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:16

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-12T21:34:10', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'b07d5d20-813e-4fcc-8ffc-8f2b7f54ffa1'	System	13 Sep 2020 01:34:24
User entered 'None (0)'	System	13 Sep 2020 01:34:24

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-12T21:34:12', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'b07d5d20-813e-4fcc-8ffc-8f2b7f54ffa1'	System	13 Sep 2020 01:34:24
User entered 'None (0)'	System	13 Sep 2020 01:34:24

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-12T21:34:13', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'b07d5d20-813e-4fcc-8ffc-8f2b7f54ffa1'	System	13 Sep 2020 01:34:24
User entered 'None (0)'	System	13 Sep 2020 01:34:24

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-12T21:34:14', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'b07d5d20-813e-4fcc-8ffc-8f2b7f54ffa1'	System	13 Sep 2020 01:34:24
User entered 'None (0)'	System	13 Sep 2020 01:34:24

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:16

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-12T21:34:15', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'b07d5d20-813e-4fcc-8ffc-8f2b7f54ffa1'	System	13 Sep 2020 01:34:24
User entered 'None (0)'	System	13 Sep 2020 01:34:24

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:16

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 (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-12T21:34:17', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'b07d5d20-813e-4fcc-8ffc-8f2b7f54ffa1'	System	13 Sep 2020 01:34:24
User entered 'No (N)'	System	13 Sep 2020 01:34:24

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:16

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-12T21:34:19', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'b07d5d20-813e-4fcc-8ffc-8f2b7f54ffa1'	System	13 Sep 2020 01:34:24
User entered '12 Sep 2020 21:34'	System	13 Sep 2020 01:34:24

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 19:07:13
User entered 'Day 3'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:16

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-13T20:08:00', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'e1eb83dd-a331-4872-be19-ccc1ff93aebe'	System	14 Sep 2020 00:08:23
User entered 'None (0)'	System	14 Sep 2020 00:08:23

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:16

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-13T20:08:03', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'e1eb83dd-a331-4872-be19-ccc1ff93aeb'	System	14 Sep 2020 00:08:23
User entered 'No interference with activity (1)'	System	14 Sep 2020 00:08:23

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-13T20:08:05', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'e1eb83dd-a331-4872-be19-ccc1ff93aebe'	System	14 Sep 2020 00:08:23
User entered 'None (0)'	System	14 Sep 2020 00:08:23

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-13T20:08:07', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'e1eb83dd-a331-4872-be19-ccc1ff93aebe'	System	14 Sep 2020 00:08:23
User entered 'None (0)'	System	14 Sep 2020 00:08:23

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-13T20:08:09', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'e1eb83dd-a331-4872-be19-ccc1ff93aebe'	System	14 Sep 2020 00:08:23
User entered 'None (0)'	System	14 Sep 2020 00:08:23

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:16

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-13T20:08:11', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'e1eb83dd-a331-4872-be19-ccc1ff93aebe'	System	14 Sep 2020 00:08:23
User entered 'None (0)'	System	14 Sep 2020 00:08:23

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:16

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 (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-13T20:08:16', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'e1eb83dd-a331-4872-be19-ccc1ff93aebe'	System	14 Sep 2020 00:08:23
User entered 'No (N)'	System	14 Sep 2020 00:08:23

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:16

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-13T20:08:18', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'e1eb83dd-a331-4872-be19-ccc1ff93aebe'	System	14 Sep 2020 00:08:23
User entered '13 Sep 2020 20:08'	System	14 Sep 2020 00:08:23

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 19:07:13
User entered 'Day 4'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:16

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-14T20:56:52', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '199c6338-ea13-4452-89b7-4a263a0f3b65'	System	15 Sep 2020 00:57:24
User entered 'None (0)'	System	15 Sep 2020 00:57:24

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:16

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-14T20:56:56', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '199c6338-ea13-4452-89b7-4a263a0f3b65'	System	15 Sep 2020 00:57:24
User entered 'No interference with activity (1)'	System	15 Sep 2020 00:57:24

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-14T20:56:58', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '199c6338-ea13-4452-89b7-4a263a0f3b65'	System	15 Sep 2020 00:57:24
User entered 'None (0)'	System	15 Sep 2020 00:57:24

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-14T20:57:00', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '199c6338-ea13-4452-89b7-4a263a0f3b65'	System	15 Sep 2020 00:57:24
User entered 'None (0)'	System	15 Sep 2020 00:57:24

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-14T20:57:01', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '199c6338-ea13-4452-89b7-4a263a0f3b65'	System	15 Sep 2020 00:57:24
User entered 'None (0)'	System	15 Sep 2020 00:57:24

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:16

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-14T20:57:03', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '199c6338-ea13-4452-89b7-4a263a0f3b65'	System	15 Sep 2020 00:57:24
User entered 'None (0)'	System	15 Sep 2020 00:57:24

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:16

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 (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-14T20:57:12', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '199c6338-ea13-4452-89b7-4a263a0f3b65'	System	15 Sep 2020 00:57:24
User entered 'Yes (Y)'	System	15 Sep 2020 00:57:24

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:16

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-14T20:57:21', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '199c6338-ea13-4452-89b7-4a263a0f3b65'	System	15 Sep 2020 00:57:24
User entered '14 Sep 2020 20:57'	System	15 Sep 2020 00:57:24

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 19:07:13
User entered 'Day 5'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:16

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-15T21:02:21', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'd39dc177-7787-4602-ac9f-04f4a2307f60'	System	16 Sep 2020 01:02:40
User entered 'No interference with activity (1)'	System	16 Sep 2020 01:02:40

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:16

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-15T21:02:25', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'd39dc177-7787-4602-ac9f-04f4a2307f60'	System	16 Sep 2020 01:02:40
User entered 'No interference with activity (1)'	System	16 Sep 2020 01:02:40

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-15T21:02:28', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'd39dc177-7787-4602-ac9f-04f4a2307f60'	System	16 Sep 2020 01:02:40
User entered 'None (0)'	System	16 Sep 2020 01:02:40

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-15T21:02:30', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'd39dc177-7787-4602-ac9f-04f4a2307f60'	System	16 Sep 2020 01:02:40
User entered 'None (0)'	System	16 Sep 2020 01:02:40

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-15T21:02:32', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'd39dc177-7787-4602-ac9f-04f4a2307f60'	System	16 Sep 2020 01:02:40
User entered 'None (0)'	System	16 Sep 2020 01:02:40

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:16

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-15T21:02:34', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'd39dc177-7787-4602-ac9f-04f4a2307f60'	System	16 Sep 2020 01:02:40
User entered 'None (0)'	System	16 Sep 2020 01:02:40

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:16

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 (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-15T21:02:36', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'd39dc177-7787-4602-ac9f-04f4a2307f60'	System	16 Sep 2020 01:02:40
User entered 'No (N)'	System	16 Sep 2020 01:02:40

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:16

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-15T21:02:37', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'd39dc177-7787-4602-ac9f-04f4a2307f60'	System	16 Sep 2020 01:02:40
User entered '15 Sep 2020 21:02'	System	16 Sep 2020 01:02:40

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 19:07:13
User entered 'Day 6'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:16

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-17T10:04:58', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'a1af1cb3-343c-4a99-8da4-4906bfadcd48'	System	17 Sep 2020 14:05:11
User entered 'None (0)'	System	17 Sep 2020 14:05:11

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:16

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-17T10:04:59', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'a1af1cb3-343c-4a99-8da4-4906bfadcd48'	System	17 Sep 2020 14:05:11
User entered 'None (0)'	System	17 Sep 2020 14:05:11

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-17T10:05:01', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'a1af1cb3-343c-4a99-8da4-4906bfadcd48'	System	17 Sep 2020 14:05:11
User entered 'None (0)'	System	17 Sep 2020 14:05:11

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-17T10:05:02', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'a1af1cb3-343c-4a99-8da4-4906bfadcd48'	System	17 Sep 2020 14:05:11
User entered 'None (0)'	System	17 Sep 2020 14:05:11

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-17T10:05:04', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'a1af1cb3-343c-4a99-8da4-4906bfadcd48'	System	17 Sep 2020 14:05:11
User entered 'None (0)'	System	17 Sep 2020 14:05:11

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:16

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-17T10:05:05', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'a1af1cb3-343c-4a99-8da4-4906bfadcd48'	System	17 Sep 2020 14:05:11
User entered 'None (0)'	System	17 Sep 2020 14:05:11

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:16

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 (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-17T10:05:07', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'a1af1cb3-343c-4a99-8da4-4906bfadcd48'	System	17 Sep 2020 14:05:11
User entered 'No (N)'	System	17 Sep 2020 14:05:11

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:16

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-09-17T10:05:09', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'a1af1cb3-343c-4a99-8da4-4906bfadcd48'	System	17 Sep 2020 14:05:11
User entered '17 Sep 2020 10:05'	System	17 Sep 2020 14:05:11

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 19:07:13
User entered 'Day 7'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:22:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 19:07:13

US3802225

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:22:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 19:07:13

US3802225

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:44:11
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 20:01:17

US3802225

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:16

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:44:11
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '18 Sep 2020'	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 20:01:17

US3802225

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:44:11
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 20:01:17

US3802225

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:44:11
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered empty.	Jennifer Nagg (b) (4)	18 Sep 2020 20:01:17

US3802225

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:44:21
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 20:01:23

US3802225

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:16

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 20:01:23

US3802225

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:44:39
User signature succeeded.	Judith Martin (b) (4)	25 Sep 2020 16:24:18
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Sep 2020 16:22:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Sep 2020 16:22:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Judith Martin (b) (4)	25 Sep 2020 16:22:10
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Sep 2020 13:27:12
User entered empty.	System	25 Sep 2020 13:27:12
	Judith Martin (b) (4)	25 Sep 2020 13:27:12
	(b) (4)	

US3802225

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:16

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:44:39
User signature succeeded.	Judith Martin (b) (4)	25 Sep 2020 16:24:18
User entered '25 Sep 2020' reason for change: Data Entry Error	Judith Martin (b) (4)	25 Sep 2020 16:22:10
User entered empty.	Judith Martin (b) (4)	25 Sep 2020 13:27:12

US3802225

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:44:39
User signature succeeded.	Judith Martin (b) (4)	25 Sep 2020 16:24:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	Judith Martin (b) (4)	25 Sep 2020 16:22:10
User entered empty.	(b) (4)	
	Judith Martin (b) (4)	25 Sep 2020 13:27:12
	(b) (4)	

US3802225

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:44:39
User signature succeeded.	Judith Martin (b) (4)	25 Sep 2020 16:24:18
User entered empty.	Judith Martin (b) (4)	25 Sep 2020 13:27:12

US3802225

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:44:46
User signature succeeded.	Judith Martin (b) (4)	25 Sep 2020 16:24:18
User entered 'Yes (Y)'	Judith Martin (b) (4)	25 Sep 2020 16:22:19

US3802225

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:16

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 16:22:19

US3802225

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:45:15
User signature succeeded.	Judith Martin (b) (4)	02 Oct 2020 15:26:43
User entered 'Yes (Y)'	Judith Martin (b) (4)	02 Oct 2020 15:26:20

US3802225

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:16

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:45:15
User signature succeeded.	Judith Martin (b) (4)	02 Oct 2020 15:26:43
User entered '2 Oct 2020'	Judith Martin (b) (4)	02 Oct 2020 15:26:20

US3802225

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:45:15
User signature succeeded.	Judith Martin (b) (4)	02 Oct 2020 15:26:43
User entered 'Contact Made (CONTACT MADE)'	Judith Martin (b) (4)	02 Oct 2020 15:26:20

US3802225

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:45:15
User signature succeeded.	Judith Martin (b) (4)	02 Oct 2020 15:26:43
User entered empty.	Judith Martin (b) (4)	02 Oct 2020 15:26:20

US3802225

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:45:26
User signature succeeded.	Judith Martin (b) (4)	02 Oct 2020 15:26:43
User entered 'Yes (Y)'	Judith Martin (b) (4)	02 Oct 2020 15:26:26

US3802225

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:16

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 15:26:26

US3802225

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:22:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	09 Oct 2020 17:30:09

US3802225

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	09 Oct 2020 17:30:09

US3802225

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	09 Oct 2020 17:30:09

US3802225

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:22:16

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	09 Oct 2020 17:30:09

US3802225

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	09 Oct 2020 17:30:17

US3802225

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:16

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 17:30:17

US3802225

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Carney (b) (4) (b) (4)	23 Nov 2020 19:26:44

US3802225

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:16

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 19:26:44

US3802225

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Carney (b) (4) (b) (4)	23 Nov 2020 19:26:56

US3802225

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:16

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 19:26:56

US3802225

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Carney (b) (4) (b) (4)	23 Nov 2020 19:27:01

US3802225

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:16

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 19:27:01

US3802225

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:22:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Carney (b) (4) (b) (4)	23 Nov 2020 19:27:10

US3802225

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Emily Carney (b) (4) (b) (4)	23 Nov 2020 19:27:10

US3802225

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:22:16

[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)	23 Nov 2020 19:27:10

US3802225

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:22:16

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	23 Nov 2020 19:27:10

US3802225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Carney (b) (4) (b) (4)	23 Nov 2020 19:27:40

US3802225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Emily Carney (b) (4) (b) (4)	23 Nov 2020 19:27:40

US3802225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
User entered '14:02'	Emily Carney (b) (4) (b) (4)	23 Nov 2020 19:27:40

US3802225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
User entered '23 Nov 2020 14:02'	System	23 Nov 2020 19:27:40

US3802225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
User entered '99.2' F	Emily Carney (b) (4) (b) (4)	23 Nov 2020 19:27:40

US3802225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Emily Carney (b) (4) (b) (4)	23 Nov 2020 19:27:40

US3802225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Infrared'	Emily Carney (b) (4) (b) (4)	23 Nov 2020 19:27:40

US3802225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '86'	Emily Carney (b) (4) (b) (4)	23 Nov 2020 19:27:40

US3802225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	23 Nov 2020 19:27:40

US3802225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
User entered '18'	Emily Carney (b) (4) (b) (4)	23 Nov 2020 19:27:40

US3802225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	23 Nov 2020 19:27:40

US3802225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
User entered '136'	Emily Carney (b) (4) (b) (4)	23 Nov 2020 19:27:40

US3802225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Nov 2020 19:27:40

US3802225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
User entered '84'	Emily Carney (b) (4) (b) (4)	23 Nov 2020 19:27:40

US3802225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Nov 2020 19:27:40

US3802225

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:22:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Carney (b) (4) (b) (4)	23 Nov 2020 19:27:45

US3802225

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:22:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Emily Carney (b) (4) (b) (4)	23 Nov 2020 19:27:45

US3802225

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:22:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Carney (b) (4) (b) (4)	23 Nov 2020 19:27:57

US3802225

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:22:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Emily Carney (b) (4) (b) (4)	23 Nov 2020 19:27:57

US3802225

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
User entered '14:12'	Emily Carney (b) (4) (b) (4)	23 Nov 2020 19:27:57

US3802225

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
User entered '23 Nov 2020 14:12'	System	23 Nov 2020 19:27:57

US3802225

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Carney (b) (4) (b) (4)	23 Nov 2020 19:28:01

US3802225

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:16

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 19:28:01

US3802225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 19:07:13
User entered 'Day 64'	System	11 Sep 2020 19:07:13

US3802225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-11-11T00:46:55', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'e882200a-695d-43e0-a427-5d4f1d1e40c9'	System	11 Nov 2020 05:49:27
User entered 'No (N)'	System	11 Nov 2020 05:49:27

US3802225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

Have you been exposed to someone with 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 (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-11-11T00:49:01', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'e882200a-695d-43e0-a427-5d4f1d1e40c9'	System	11 Nov 2020 05:49:27
User entered 'Yes (Y)'	System	11 Nov 2020 05:49:27

US3802225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Please 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 (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-11-11T00:49:12', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'e882200a-695d-43e0-a427-5d4f1d1e40c9'	System	11 Nov 2020 05:49:27
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Nov 2020 05:49:27

US3802225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-11-11T00:49:17', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: 'e882200a-695d-43e0-a427-5d4f1d1e40c9' User entered '11 Nov 2020 00:49:17'	System	11 Nov 2020 05:49:27
	System	11 Nov 2020 05:49:27

US3802225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 19:07:13
User entered '11 Nov 2020 00:01'	System	11 Sep 2020 19:07:13

US3802225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 19:07:13
User entered '15 Nov 2020 23:59'	System	11 Sep 2020 19:07:13

US3802225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 19:07:13
User entered 'Day 71'	System	11 Sep 2020 19:07:13

US3802225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

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 (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-11-18T00:09:36', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '2510e3ab-1b9b-4b96-9b15-c2ec24857404'	System	18 Nov 2020 05:09:52
User entered 'No (N)'	System	18 Nov 2020 05:09:52

US3802225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

Have you been exposed to someone with 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 (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-11-18T00:09:46', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '2510e3ab-1b9b-4b96-9b15-c2ec24857404'	System	18 Nov 2020 05:09:52
User entered 'No (N)'	System	18 Nov 2020 05:09:52

US3802225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D263DD2-0623-4276-9114-981AAB5F4021)', Time: '2020-11-18T00:09:50', User OID: 'PatientReportedOutcome (US3802225)', ODM File OID: '2510e3ab-1b9b-4b96-9b15-c2ec24857404'	System	18 Nov 2020 05:09:52
User entered '18 Nov 2020 00:09:50'	System	18 Nov 2020 05:09:52

US3802225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 19:07:13
User entered '18 Nov 2020 00:01'	System	11 Sep 2020 19:07:13

US3802225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 19:07:13
User entered '22 Nov 2020 23:59'	System	11 Sep 2020 19:07:13

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '08 Nov 2020 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '12 Nov 2020 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '15 Nov 2020 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '19 Nov 2020 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 07:47:45

US3802225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:47:45
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 07:47:45

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:22:16

[Date of Contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '18 Sep 2020'	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 19:37:09

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:22:16

[Time of Contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '15:00'	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 19:37:09

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:22:16

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 15:00'	System	18 Sep 2020 19:37:09

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:22:16

[Type of Contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Safety Call (Safety Call)'	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 19:37:09

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:22:16

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Signature has been broken.	Jennifer Nagg (b) (4)	11 Nov 2020 13:50:52
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	11 Nov 2020 13:50:52
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Yes (Y)'	Jennifer Nagg (b) (4)	18 Sep 2020 19:37:09

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:22:16

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Day 1 (Day 1)'	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 19:38:26

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:22:16

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '18 Sep 2020'	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 19:38:26

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:22:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '0'	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 19:38:26

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:22:16

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 19:38:26

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:22:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:38:26

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:22:16

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 19:38:26

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:22:16

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 19:38:26

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:22:16

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 19:38:26

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:22:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 19:38:26

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:22:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 19:38:26

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:22:16

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 19:38:26

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:22:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 19:38:26

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:22:16

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 19:38:26

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:22:16

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 19:38:26

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:22:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 19:38:26

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:22:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Mild (Mild)'	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 19:38:26

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:22:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 19:38:26

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:22:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 19:38:26

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:22:16

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 19:38:26

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:22:16

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 19:38:26

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:22:16

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 19:38:26

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:22:16

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 19:38:26

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:22:16

[Date of Visit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '11 Sep 2020'	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 19:59:11

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:22:16

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 19:59:11

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:22:16

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
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). User signature succeeded.	(b) (4), (b) (6) (b) (4)	28 Sep 2020 13:10:12
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 'positive at enrollment visit' (Site from System).	Judith Martin (b) (4) (b) (4)	19 Sep 2020 11:08:19
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).	Jennifer Nagg (b) (4) (b) (4)	18 Sep 2020 19:59:36
User entered 'Yes (Y)'	System	18 Sep 2020 19:59:11
	Jennifer Nagg (b) (4) (b) (4)	18 Sep 2020 19:59:11

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:22:16

[Date of Test](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 11Sep2020 is recorded under Covid Diagnostic test in EDC, however the same sample is reported under V1 Day 1 visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' answered with 'he was found to be positive at the enrollment visit, a sick visit was not done' (Site from DM).	Jennifer Nagg (b) (4)	11 Nov 2020 13:53:52
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 11Sep2020 is recorded under Covid Diagnostic test in EDC, however the same sample is reported under V1 Day 1 visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 03:59:04
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '11 Sep 2020'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	18 Sep 2020 19:59:11

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:22:16

[Type of Test Performed](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 19:59:11

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:22:16

[Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 19:59:11

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:22:16

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'No (N)'	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 19:59:11

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:22:16

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 19:59:11
	(b) (4)	

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:22:16

[CLIA Certified?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 19:59:11

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:22:16

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:59:11

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

Did the subject have Respiratory Rates $\geq$ 30 per Minute?

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[Respiratory Rate](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

Did the subject have Heart Rate $\geq$ 125 beats per minute

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[Heart Rate](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

Did the subject have Oxygen Saturation of $\text{SpO}_2 \leq 93\%$ on room air at sea level?

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[Oxygen Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[PaO2](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[Did the subject have Acute Respiratory Distress Syndrome \(ARDS\)?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[ECMO?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[Clinical Evidence](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[Date of Assessment](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[Radiographical Evidence](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[Date of Assessment](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:22:16

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:56:49

US3802225

Folder: Covid-19 Assessment 18 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:22:16

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	11 Nov 2020 13:51:27

US3802225

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:22:16

[Visit](#)

Audit	User	Time (GMT)
Amendment Manager: User entered 'Day 3 (Day 3)'	System	20 Nov 2020 07:47:31
Amendment Manager: User entered 'Day 3 (Day 3)'	System	23 Oct 2020 08:17:08

US3802225

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 11:22:16

[Visit](#)

Audit	User	Time (GMT)
Amendment Manager: User entered 'Day 5 (Day 5)'	System	20 Nov 2020 07:47:31
Amendment Manager: User entered 'Day 5 (Day 5)'	System	23 Oct 2020 08:17:08

US3802225

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 11:22:16

[Visit](#)

Audit	User	Time (GMT)
Amendment Manager: User entered 'Day 7 (Day 7)'	System	20 Nov 2020 07:47:31
Amendment Manager: User entered 'Day 7 (Day 7)'	System	23 Oct 2020 08:17:08

US3802225

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:22:16

[Visit](#)

Audit	User	Time (GMT)
Amendment Manager: User entered 'Day 9 (Day 9)'	System	20 Nov 2020 07:47:31
Amendment Manager: User entered 'Day 9 (Day 9)'	System	23 Oct 2020 08:17:08

US3802225

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:22:16

[Visit](#)

Audit	User	Time (GMT)
Amendment Manager: User entered 'Day 14 (Day 14)'	System	20 Nov 2020 07:47:31
Amendment Manager: User entered 'Day 14 (Day 14)'	System	23 Oct 2020 08:17:08

US3802225

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:22:16

[Visit](#)

Audit	User	Time (GMT)
Amendment Manager: User entered 'Day 21 (Day 21)'	System	20 Nov 2020 07:47:31
Amendment Manager: User entered 'Day 21 (Day 21)'	System	23 Oct 2020 08:17:08

US3802225

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:22:16

[Visit](#)

Audit	User	Time (GMT)
Amendment Manager: User entered 'Day 28 (Day 28)'	System	20 Nov 2020 07:47:31
Amendment Manager: User entered 'Day 28 (Day 28)'	System	23 Oct 2020 08:17:08

US3802225

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:22:16

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	02 Oct 2020 15:26:43
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 18:50:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Sep 2020 18:50:24
User entered 'No (N)' reason for change: Data Entry Error	Melissa Andrasko (b) (4)	25 Sep 2020 18:50:24
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 18:50:15
User entered empty; reason for change Data Entry Error	Melissa Andrasko (b) (4)	25 Sep 2020 18:50:15
User entered 'No (N)' reason for change: Data Entry Error	Melissa Andrasko (b) (4)	25 Sep 2020 18:50:01
User entered 'Yes (Y)'	Melissa Andrasko (b) (4)	25 Sep 2020 18:44:13

US3802225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:22:16

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Signature has been broken.	Emily Carney (b) (4)	23 Nov 2020 19:28:36
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Emily Carney (b) (4)	23 Nov 2020 19:28:36
	(b) (4)	
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
	(b) (4)	
User entered 'No (N)'	Matthew Lee (b) (4)	11 Sep 2020 19:15:39
	(b) (4)	

US3802225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:16

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 20:01:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 20:01:08
Data point term sent to Coder	System	23 Nov 2020 19:30:26
User entered 'Influenza vaccine'	Emily Carney (b) (4)	23 Nov 2020 19:29:43

US3802225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emily Carney (b) (4) (b) (4)	23 Nov 2020 19:29:43

US3802225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:16

[Indication](#)

Audit	User	Time (GMT)
User entered 'Prevent influenza infection'	Emily Carney (b) (4) (b) (4)	23 Nov 2020 19:29:43

US3802225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:16

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '0.5'	Emily Carney (b) (4) (b) (4)	23 Nov 2020 19:29:43

US3802225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:16

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mL (mL)'	Emily Carney (b) (4) (b) (4)	23 Nov 2020 19:29:43

US3802225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Emily Carney (b) (4) (b) (4)	23 Nov 2020 19:29:43

US3802225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:16

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Emily Carney (b) (4) (b) (4)	23 Nov 2020 19:29:43

US3802225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Emily Carney (b) (4) (b) (4)	23 Nov 2020 19:29:43

US3802225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:16

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	Emily Carney (b) (4) (b) (4)	23 Nov 2020 19:29:43

US3802225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Emily Carney (b) (4) (b) (4)	23 Nov 2020 19:29:43

US3802225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:16

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

Audit	User	Time (GMT)
User entered '10 Nov 2020'	Emily Carney (b) (4) (b) (4)	23 Nov 2020 19:29:43

US3802225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Emily Carney (b) (4) (b) (4)	23 Nov 2020 19:29:43

US3802225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:16

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Carney (b) (4) (b) (4)	23 Nov 2020 19:29:43

US3802225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '10 Nov 2020'	Emily Carney (b) (4) (b) (4)	23 Nov 2020 19:29:43

US3802225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Emily Carney (b) (4) (b) (4)	23 Nov 2020 19:29:43

US3802225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 19:29:43

US3802225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 19:29:43

US3802225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 19:29:43

US3802225

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:22:16

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Per pages 38-39 of CCGs, "Date of dosing discontinuation" should be the same as date of last exposure. If the subject discontinues the study as well (i.e. not being followed) please fill in the "End of Study/Study Discontinuation" form and date it with the date of last contact. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 08:29:51
Query 'Per CDM: Per pages 38-39 of CCGs, "Date of dosing discontinuation" should be the same as date of last exposure. If the subject discontinues the study as well (i.e. not being followed) please fill in the "End of Study/Study Discontinuation" form and date it with the date of last contact. Thank you.' answered with 'Discontinued IP date is date of COVID +results, subject will continue to be followed.' (Site from DM).	Jennifer Nagg (b) (4)	16 Oct 2020 00:31:20
User opened query 'Per CDM: Per pages 38-39 of CCGs, "Date of dosing discontinuation" should be the same as date of last exposure. If the subject discontinues the study as well (i.e. not being followed) please fill in the "End of Study/Study Discontinuation" form and date it with the date of last contact. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 07:38:56
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered '15 Sep 2020'	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 20:13:34

US3802225

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:22:16

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Query 'Per CDM: Per CCGs page 38 (enter due to SARS-COV-2 if participant is diagnosed). Please confirm if patient was diagnosed. Also complete the Covid-19 Assessment page. Verify and consider updating all the required eCRFs, else clarify. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 07:41:56
User opened query 'Per CDM: Per CCGs page 38 (enter due to SARS-COV-2 if participant is diagnosed). Please confirm if patient was diagnosed. Also complete the Covid-19 Assessment page. Verify and consider updating all the required eCRFs, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 07:41:14
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered 'Due to SARS-COV-2 (COVID)'	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 20:13:34

US3802225

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:22:16

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Sep 2020 11:08:19
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	18 Sep 2020 20:13:34