

US3842060 (Prod: New Jersey Medical School)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:57:00

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US3842060

Form: Participant Creation

Generated On: 26 Nov 2020 09:57:00

[Participant ID](#)

US3842060

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

US3842060

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:57:00

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

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:57:00

Date of Birth (MMM yyyy)	(b) (6) 1963
Age	57
Age Units	YEARS
Age (Derived)	57
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☒ Not Hispanic or Latino ☐ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	False
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	True
If race is Other, specify	CUBAN
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:57:00

Date of Informed Consent (<i>dd MMM yyyy</i>)	21 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☐
	Amendment 3 ☐
	Amendment 4 ☒
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:57:00

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:57:00

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:57:00

Condition	SEASONAL RHINITIS
Start date (dd MMM yyyy)	UN UNK 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)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:57:00

Condition	HERNIATED DISK T10 T11
Start date (dd MMM yyyy)	UN UNK 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)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:57:00

Condition	RIGHT ROTATOR CUFF SURGERY
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:57:00

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

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:57:00

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	21 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	13:09 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 13:09
Height (<i>xxx.x</i>)	174.5 cm
Weight (<i>xxx.x</i>)	88.3 kg
BMI (<i>xxx.x</i>)	28.99812 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:57:00

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 OCT 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

Generated On: 26 Nov 2020 09:57:00

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

CORRECTIONS

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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

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Folder: Screening

Form: Risk of Exposure

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Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:57:00

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	21 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:57:00

What was the date of randomization? (dd MMM yyyy) 21 OCT 2020

What was the participant's randomization number? 117719

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:57:00

Height	
Weight	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:57:00

Height	
Weight	
Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	21 OCT 2020
Time of assessment (00:00-23:59)	13:09 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 13:09
Temperature (xxx.x)	98.2 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:57:00

Height	
Weight	
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	21 OCT 2020
Time of assessment (00:00-23:59)	16:11 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 16:11
Temperature (xxx.x)	98.0 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:57:00

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.

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:57:00

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)	21 OCT 2020
What was the treatment time? (00:00-23:59)	15:40 (24 HR)
Treatment Date and Time (derived)	21 OCT 2020 15:40
Which arm was used to give treatment?	Left Arm ☒
	Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:57:00

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	21 OCT 2020
Collection time (<i>00:00-23:59</i>)	13:52 (24 HR)
Collection date and time (derived)	21 OCT 2020 13:52

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:57:00

Collection date (<i>dd MMM yyyy</i>)			21 OCT 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:58	21 OCT 2020 13:58
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:57:00

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 09:57:00

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

21 OCT 2020 16:16

PC Open Date & Time

21 OCT 2020 16:00

PC Close Date & Time

21 OCT 2020 18:30

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.2 °F

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

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

PC Time Stamp	21 OCT 2020 20:17
PC Open Date & Time	21 OCT 2020 19:25
PC Close Date & Time	22 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:57:00

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

97.0 °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

22 OCT 2020 17:12

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:57:00

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

96.3 °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

23 OCT 2020 12:03

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:57:00

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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 OCT 2020 13:01

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:57:00

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

96.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 OCT 2020 13:11

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

95.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 OCT 2020 16:38

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 OCT 2020 19:00

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:57:00

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

21 OCT 2020 16:20

PC Open Date & Time

21 OCT 2020 16:00

PC Close Date & Time

21 OCT 2020 18:30

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:57:00

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

21 OCT 2020 20:18

PC Open Date & Time

21 OCT 2020 19:25

PC Close Date & Time

22 OCT 2020 11:59

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:57:00

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

22 OCT 2020 17:12

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:57:00

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

23 OCT 2020 12:03

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:57:00

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

24 OCT 2020 13:01

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:57:00

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

25 OCT 2020 13:12

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:57:00

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

26 OCT 2020 16:39

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 OCT 2020 19:01

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:57:00

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

No ☒

Yes ☐

PC Time stamp	21 OCT 2020 16:21
PC Open Date & Time	21 OCT 2020 16:00
PC Close Date & Time	21 OCT 2020 18:30

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:57:00

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

No ☒

Yes ☐

PC Time stamp	21 OCT 2020 20:19
PC Open Date & Time	21 OCT 2020 19:25
PC Close Date & Time	22 OCT 2020 11:59

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:57:00

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 ☒

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:57:00

Yes ☐	
PC Time stamp	22 OCT 2020 17:13
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:57:00

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 ☒

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:57:00

Yes ☐	
PC Time stamp	23 OCT 2020 12:04
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:57:00

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 ☒

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:57:00

Yes ☐	
PC Time stamp	24 OCT 2020 13:02
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:57:00

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 ☒

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:57:00

Yes ☐	
PC Time stamp	25 OCT 2020 13:12
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:57:00

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 ☒

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:57:00

Yes ☐	
PC Time stamp	26 OCT 2020 16:39
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:57:00

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 ☒

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:57:00

Yes ☐	
PC Time stamp	27 OCT 2020 19:02
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3842060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:57:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3842060

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:57:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:57:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3842060

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:57:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:57:00

Was Contact Attempted?

Yes ☒

No ☐

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

13 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3842060

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:57:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:57:00

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	18 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:57:00

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	18 NOV 2020
Time of assessment (00:00-23:59)	14:21 (24 HR)
Vital Signs Date and Time (derived)	18 NOV 2020 14:21
Temperature (xxx.x)	98.1 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:57:00

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	

US3842060

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:57:00

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.

US3842060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:57:00

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

PROTOCOL DIRECTIVE VIA EPIP HAS REQUESTED THAT 2ND DOSE NOT BE ADMINISTERED. PARTICIPANT HAD A POSITIVE SALIVA TEST THAT WAS ADMINISTERED AT HIS WORKSITE.

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? _____

US3842060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:57:00

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	18 NOV 2020
Collection time (<i>00:00-23:59</i>)	14:40 (24 HR)
Collection date and time (derived)	18 NOV 2020 14:40

US3842060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:57:00

Collection date (<i>dd MMM yyyy</i>)			18 NOV 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:42	18 NOV 2020 14:42
Nasopharyngeal Swab 2	No		

US3842060

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:57:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842060

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:57:00

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

US3842060

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:57:00

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2020 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2020 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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°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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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°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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

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28 JUN 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

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05 JUL 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

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12 JUL 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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15 JUL 2022 00:01

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19 JUL 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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22 JUL 2022 00:01

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26 JUL 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

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02 AUG 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

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09 AUG 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

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16 AUG 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

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23 AUG 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

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30 AUG 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

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06 SEP 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

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13 SEP 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

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16 SEP 2022 00:01

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20 SEP 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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°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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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 ☐

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2022 23:59

US3842060

Folder: Covid-19 Assessment 29 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:57:00

Date of Contact	29 OCT 2020
Time of Contact	03:46
Date and Time of Contact (derived)	29 OCT 2020 03:46
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 ☒

US3842060

Folder: Covid-19 Assessment 29 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:57:00

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3842060

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:57:00

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

AEID	
Adverse event	A-SYMPTOMATIC COVID-19
Was this a medically-attended AE?	Yes ☐ No ☒
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	26 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	26 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

v6.020 DTW (1102)

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US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☒ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PARTICIPANT POSITIVE ON LOCAL SALIVA TEST, REPORTED A-SYMPTOMATIC. CONFIRMED WITH PPD, PER PROTOCOL PARTICIPANT DISCONTINUED FROM RECEIVING STUDY PRODUCT. WILL CONTINUE STUDY SCHEDULES AND PROCEDURES.
Serious Adverse Event Derived (CSA Programming Field Only)	0
v6.020 DTW (1102)	289 of 1279

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

AEID	
Adverse event	ANXIETY
Was this a medically-attended AE?	Yes ☐ No ☒
Was this a Solicited Adverse Reaction?	Yes ☒ No ☐
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	17 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	17 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

v6.020 DTW (1102)

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US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	ANXIETY RELATED TO MRI INDUCED CLAUSTROPHOBIA
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

AEID	
Adverse event	CLAUSTROPHOBIA
Was this a medically-attended AE?	Yes ☐ No ☒
Was this a Solicited Adverse Reaction?	Yes ☒ No ☐
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	17 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	17 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

v6.020 DTW (1102)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	CLAUSTROPHOBIA INDUCED BY MRI
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:57:00

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

Yes ☒

No ☐

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

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:57:00

Name of Medication	SIMVASTATIN
Prophylaxis	Yes ☒ No ☐
Indication	REDUCE RISK OF MI OR BRAIN ATTACK
Dose per administration	20
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☒
If frequency is Other, specify	
Route of administration	OCCASIONAL Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:57:00

	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)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:57:00

Name of Medication	VITAMIN B12
Prophylaxis	Yes ☒ No ☐
Indication	NUTRITIONAL SUPPLEMENT
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☒ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:57:00

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:57:00

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

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:57:00

	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)		17 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		17 NOV 2020
Was this medication taken for solicited event?	Yes	☒
	No	☐
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3842060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:57:00

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3842060

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:57:00

Date of dosing discontinuation (dd MMM yyyy)

26 OCT 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

US3842060

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:57:00

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

US3842060 (Prod: New Jersey Medical School)

US3842060

Form: Participant Creation

Generated On: 26 Nov 2020 09:57:00

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3842060'	RWS_ENDPOINT ENDPOINT (b) (4) 	21 Oct 2020 16:33:42

US3842060

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:57:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:13:20

US3842060

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '21 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	21 Oct 2020 16:33:43

US3842060

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:13:20

US3842060

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:57:00

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	21 Oct 2020 19:13:20

US3842060

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:57:00

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Recon: Antibody-mediated Immunogenicity- Sex (Male) and Year of Birth (1963) recorded on this form however same is missing in PPD central lab. Please reconcile the data and update as needed. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 11:27:56
Query 'Per GCL Lab Recon: Antibody-mediated Immunogenicity- Sex (Male) and Year of Birth (1963) recorded on this form however same is missing in PPD central lab. Please reconcile the data and update as needed. Else clarify, thank you.' answered with 'Will notify the missing month of birth to the lab to update.' (Site from DM).	Zoraida Cruz (b) (4)	04 Nov 2020 00:26:35
User opened query 'Per GCL Lab Recon: Antibody-mediated Immunogenicity- Sex (Male) and Year of Birth (1963) recorded on this form however same is missing in PPD central lab. Please reconcile the data and update as needed. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 09:16:21
User entered (b) (6) 1963'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 16:33:44

US3842060

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:57:00

[Age](#)

Audit	User	Time (GMT)
User entered '57'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:13:47

US3842060

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:57:00

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	21 Oct 2020 19:13:47

US3842060

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:57:00

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '57'	System	21 Oct 2020 19:14:14

US3842060

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:57:00

Sex

Audit	User	Time (GMT)
User entered 'Male (M)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:13:47

US3842060

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:57:00

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:13:47

US3842060

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:57:00

White

Audit	User	Time (GMT)
User entered '0'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:13:47

US3842060

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:57:00

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:13:47

US3842060

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:57:00

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:13:47

US3842060

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:57:00

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:13:47

US3842060

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:57:00

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:13:47

US3842060

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:57:00

[Other](#)

Audit	User	Time (GMT)
User entered '1'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:13:47

US3842060

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:57:00

If race is Other, specify

Audit	User	Time (GMT)
User entered 'Cuban'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:13:47

US3842060

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:57:00

Unknown

Audit	User	Time (GMT)
User entered '0'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:13:47

US3842060

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:57:00

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:13:47

US3842060

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '21 Oct 2020'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:14:14

US3842060

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered 'Oct 2020'	System	21 Oct 2020 19:14:14

US3842060

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '2020'	System	21 Oct 2020 19:14:14

US3842060

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:57:00

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 4 (4)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:14:14

US3842060

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:14:14

US3842060

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:57:00

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:14:14

US3842060

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:57:00

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:14:14

US3842060

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:57:00

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:14:14

US3842060

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:57:00

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	21 Oct 2020 16:33:43

US3842060

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:57:00

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 19:14:22

US3842060

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:14:22

US3842060

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:57:00

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:16:54

US3842060

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:57:00

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal rhinitis - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 19:18:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 19:18:34
Data point term sent to Coder	System	21 Oct 2020 19:17:42
User entered 'Seasonal Rhinitis'	Zoraida Cruz (b) (4)	21 Oct 2020 19:17:25
	(b) (4)	

US3842060

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2020'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:17:25

US3842060

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:57:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:17:25

US3842060

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:57:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:17:25

US3842060

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:17:25

US3842060

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:57:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:17:25

US3842060

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered 'Jan 2020'	System	21 Oct 2020 19:17:25

US3842060

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '2020'	System	21 Oct 2020 19:17:25

US3842060

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 19:17:25

US3842060

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 19:17:25

US3842060

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:57:00

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Thoracic disc herniation - version MedDRA\\23.0.	Coder Import (b) (4)	22 Oct 2020 06:54:40
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	22 Oct 2020 06:54:40
Data point term sent to Coder	System	21 Oct 2020 19:19:46
User entered 'Herniated Disk T10 T11'	Zoraida Cruz (b) (4)	21 Oct 2020 19:19:15

US3842060

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2020'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:19:15

US3842060

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:57:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:19:15

US3842060

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:57:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:19:15

US3842060

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:19:15

US3842060

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:57:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:19:15

US3842060

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered 'Jan 2020'	System	21 Oct 2020 19:19:15

US3842060

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '2020'	System	21 Oct 2020 19:19:15

US3842060

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 19:19:15

US3842060

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 19:19:15

US3842060

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:57:00

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 19:22:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 19:22:36
Data point term sent to Coder	System	21 Oct 2020 19:21:49
User entered 'Right Rotator Cuff Surgery'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:20:49

US3842060

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2008'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:20:49

US3842060

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:57:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:20:49

US3842060

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:57:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:20:49

US3842060

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2008'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:20:49

US3842060

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:57:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:20:49

US3842060

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	21 Oct 2020 19:20:49

US3842060

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '2008'	System	21 Oct 2020 19:20:49

US3842060

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	21 Oct 2020 19:20:49

US3842060

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '2008'	System	21 Oct 2020 19:20:49

US3842060

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:57:00

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Herniated disc - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 07:13:44
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 07:13:44
Data point term sent to Coder	System	21 Oct 2020 19:26:00
User entered 'Chronic Leg Weakness (both) herniated disk'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:25:35

US3842060

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:25:35

US3842060

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:57:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:25:35

US3842060

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:57:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:25:35

US3842060

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:25:35

US3842060

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:57:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:25:35

US3842060

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	21 Oct 2020 19:25:35

US3842060

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '2010'	System	21 Oct 2020 19:25:35

US3842060

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 19:25:35

US3842060

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 19:25:35

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:57:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:28:23

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:57:00

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	21 Oct 2020 19:29:11
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	21 Oct 2020 19:29:11
User closed query 'The Assessment Date is before the System Date of Informed Consent. Please review and reconcile.' (Site from System).		21 Oct 2020 19:29:11
User entered '21 Oct 2020' reason for change: Data Entry Error	Malithi Desilva (b) (4)	21 Oct 2020 19:29:11
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	21 Oct 2020 19:28:23
User opened query 'The Assessment Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	21 Oct 2020 19:28:23
User entered '20 Oct 2020'	Zoraida Cruz (b) (4)	21 Oct 2020 19:28:23

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '13:09'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:28:23

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '21 Oct 2020 13:09'	System	21 Oct 2020 19:29:11
User entered '20 Oct 2020 13:09'	System	21 Oct 2020 19:28:23

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '174.5' cm	Zoraida Cruz (b) (4)	21 Oct 2020 19:28:23
DataPoint set to visible.	(b) (4) System	21 Oct 2020 19:14:22

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '88.3' kg	Zoraida Cruz (b) (4)	21 Oct 2020 19:28:23
DataPoint set to visible.	(b) (4) System	21 Oct 2020 19:14:22

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:57:00

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '28.99812'	System	21 Oct 2020 19:28:23
DataPoint set to visible.	System	21 Oct 2020 19:14:22

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:57:00

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	21 Oct 2020 19:28:23
DataPoint set to visible.	System	21 Oct 2020 19:14:22

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:57:00

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:28:23

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:57:00

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:28:23

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:57:00

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:28:23

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:57:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:28:23

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:57:00

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Oct 2020 19:28:23

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:28:23

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:57:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Oct 2020 19:28:23

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:57:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:28:23

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:57:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 19:28:23

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:28:23

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:57:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 19:28:23

US3842060

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:57:00

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:28:52

US3842060

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:57:00

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	21 Oct 2020 19:29:00
User closed query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	21 Oct 2020 19:29:00
User entered '21 Oct 2020' reason for change: Data Entry Error	Zoraida Cruz (b) (4)	21 Oct 2020 19:29:00
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	21 Oct 2020 19:28:52
User opened query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	21 Oct 2020 19:28:52
User entered '20 Oct 2020'	Zoraida Cruz (b) (4)	21 Oct 2020 19:28:52

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 19:03:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:03:37
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	26 Oct 2020 19:03:37
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:31:56
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:31:56

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 19:03:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:03:37
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	26 Oct 2020 19:03:37
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:31:56
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:31:56

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 19:03:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:03:37
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	26 Oct 2020 19:03:37
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:31:56
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:31:56

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 19:03:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:03:37
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	26 Oct 2020 19:03:37
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:31:56
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:31:56

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 19:03:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:03:37
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	26 Oct 2020 19:03:37
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:31:56
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:31:56

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 19:03:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:03:37
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	26 Oct 2020 19:03:37
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:31:56
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:31:56

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 19:03:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:03:37
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	26 Oct 2020 19:03:37
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:31:56
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:31:56

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 19:03:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:03:37
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	26 Oct 2020 19:03:37
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:31:56
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:31:56

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 19:03:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:03:37
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	26 Oct 2020 19:03:37
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:31:56
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:31:56

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 19:03:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:03:37
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	26 Oct 2020 19:03:37
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:31:56
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:31:56

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 19:03:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:03:37
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	26 Oct 2020 19:03:37
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:31:56
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:31:56

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:57:00

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:31:56

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:57:00

[Specify](#)

Audit	User	Time (GMT)
User entered 'Corrections'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:31:56

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:57:00

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:31:56

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '0'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:31:56

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '0'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:31:56

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '0'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:31:56

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '0'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:31:56

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '1'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:31:56

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:57:00

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:31:56

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:57:00

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:31:56

US3842060

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:57:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:32:11

US3842060

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '21 Oct 2020'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:32:11

US3842060

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:32:11

US3842060

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:57:00

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	21 Oct 2020 19:32:11

US3842060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '21 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	21 Oct 2020 17:43:39

US3842060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '117719'	RWS_ENDPOINT ENDPOINT (b) (4) 	21 Oct 2020 17:43:39

US3842060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	21 Oct 2020 17:43:39

US3842060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 19:02:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:02:20
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	26 Oct 2020 19:02:20
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:32:29
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:32:29

US3842060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 19:02:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:02:20
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	26 Oct 2020 19:02:20
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:32:29
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:32:29

US3842060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 19:02:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:02:20
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	26 Oct 2020 19:02:20
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:32:29
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:32:29

US3842060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 19:02:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:02:20
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	26 Oct 2020 19:02:20
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:32:29
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:32:29

US3842060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:57:00

[Liver Disease](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 19:02:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:02:20
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	26 Oct 2020 19:02:20
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:32:29
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:32:29

US3842060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 19:02:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:02:20
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	26 Oct 2020 19:02:20
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:32:29
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:32:29
DataPoint set to visible.	System	21 Oct 2020 19:14:14

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:57:00

Height

Audit	User	Time (GMT)
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:57:00

Weight

Audit	User	Time (GMT)
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:57:00

Height

Audit	User	Time (GMT)
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:57:00

Weight

Audit	User	Time (GMT)
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:57:00

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:57:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:57:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Oct 2020'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '13:09'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '21 Oct 2020 13:09'	System	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:57:00

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.2' F	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:57:00

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:57:00

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:57:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '72'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:57:00

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '16'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:57:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:57:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '139'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:57:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:57:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '87'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:57:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:57:00

Height

Audit	User	Time (GMT)
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:57:00

Weight

Audit	User	Time (GMT)
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:57:00

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:57:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:57:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Oct 2020'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '16:11'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '21 Oct 2020 16:11'	System	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:57:00

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.0' F	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:57:00

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:57:00

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:57:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '65'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:57:00

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '16'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:57:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:57:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '133'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:57:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:57:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '85'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:57:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:57:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:49:01

US3842060

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:57:00

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:49:01

US3842060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:57:00

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:49:42

US3842060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:57:00

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:49:42

US3842060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:49:42

US3842060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:57:00

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	21 Oct 2020 19:49:42

US3842060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:57:00

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '21 Oct 2020'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:49:42

US3842060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '15:40'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:49:42

US3842060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '21 Oct 2020 15:40'	System	21 Oct 2020 19:49:42

US3842060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:49:42

US3842060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	21 Oct 2020 19:49:42

US3842060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	21 Oct 2020 19:49:42

US3842060

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:57:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:50:37

US3842060

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:57:00

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	21 Oct 2020 19:50:56
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		21 Oct 2020 19:50:56
User closed query 'The Collection Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	21 Oct 2020 19:50:56
User closed query 'The Collection Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	21 Oct 2020 19:50:56
User entered '21 Oct 2020' reason for change: Data Entry Error	Zoraida Cruz (b) (4)	21 Oct 2020 19:50:56
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	21 Oct 2020 19:50:37
User opened query 'The Collection Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	21 Oct 2020 19:50:37
User opened query 'The Collection Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	21 Oct 2020 19:50:37
User entered '20 Oct 2020'	Zoraida Cruz (b) (4)	21 Oct 2020 19:50:37

US3842060

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:57:00

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '13:52'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:50:37

US3842060

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '21 Oct 2020 13:52'	System	21 Oct 2020 19:50:56
User entered '20 Oct 2020 13:52'	System	21 Oct 2020 19:50:37

US3842060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:57:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Oct 2020'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:51:30

US3842060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:57:00

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:51:30

US3842060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:57:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:51:30

US3842060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:57:00

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '13:58'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:51:30

US3842060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '21 Oct 2020 13:58'	System	21 Oct 2020 19:51:30

US3842060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:57:00

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:51:30

US3842060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:57:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:51:30

US3842060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:57:00

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:51:30

US3842060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 19:51:30

US3842060

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:51:46

US3842060

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:57:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 19:51:46

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:57:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T16:16:05', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '4dd00882-fee8-4425-942a-acb60eccde5f'	System	21 Oct 2020 20:16:30
User entered 'Yes (Y)'	System	21 Oct 2020 20:16:30

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:57:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T16:16:14', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '4dd00882-fee8-4425-942a-acb60eccde5f' User entered '98.0'	System	21 Oct 2020 20:16:30
	System	21 Oct 2020 20:16:30

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T16:16:22', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '4dd00882-fee8-4425-942a-acb60eccde5f'	System	21 Oct 2020 20:16:30
User entered 'No (N)'	System	21 Oct 2020 20:16:30

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:57:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T16:16:26', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '4dd00882-fee8-4425-942a-acb60eccde5f' User entered '21 Oct 2020 16:16'	System	21 Oct 2020 20:16:30
	System	21 Oct 2020 20:16:30

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:57:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 16:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:57:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 18:30'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 1, after vaccination (at home)'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:57:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T20:14:54', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f0c50f81-4b15-4fe5-9003-202d092432dc'	System	22 Oct 2020 00:17:30
User entered 'Yes (Y)'	System	22 Oct 2020 00:17:30

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:57:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T20:17:17', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f0c50f81-4b15-4fe5-9003-202d092432dc' User entered '97.2'	System	22 Oct 2020 00:17:30

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T20:17:23', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f0c50f81-4b15-4fe5-9003-202d092432dc'	System	22 Oct 2020 00:17:30
User entered 'No (N)'	System	22 Oct 2020 00:17:30

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:57:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T20:17:27', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f0c50f81-4b15-4fe5-9003-202d092432dc' User entered '21 Oct 2020 20:17'	System	22 Oct 2020 00:17:30
	System	22 Oct 2020 00:17:30

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:57:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 19:25'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:57:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 2'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:57:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-22T17:11:54', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '7195ebf8-38d9-4f04-9181-ec0115e56497'	System	22 Oct 2020 21:12:08
User entered 'Yes (Y)'	System	22 Oct 2020 21:12:08

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:57:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-22T17:12:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '7195ebf8-38d9-4f04-9181-ec0115e56497'	System	22 Oct 2020 21:12:08
User entered '97.0'	System	22 Oct 2020 21:12:08

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-22T17:12:03', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '7195ebf8-38d9-4f04-9181-ec0115e56497'	System	22 Oct 2020 21:12:08
User entered 'No (N)'	System	22 Oct 2020 21:12:08

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:57:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-22T17:12:06', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '7195ebf8-38d9-4f04-9181-ec0115e56497'	System	22 Oct 2020 21:12:08
User entered '22 Oct 2020 17:12'	System	22 Oct 2020 21:12:08

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:57:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:57:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 3'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:57:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-23T12:02:33', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'd23d8533-cdef-437f-a1d3-a46e752d6300'	System	23 Oct 2020 16:05:15
User entered 'Yes (Y)'	System	23 Oct 2020 16:05:15

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:57:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-23T12:03:01', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'd23d8533-cdef-437f-a1d3-a46e752d6300'	System	23 Oct 2020 16:05:15
User entered '96.3'	System	23 Oct 2020 16:05:15

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-23T12:03:08', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'd23d8533-cdef-437f-a1d3-a46e752d6300'	System	23 Oct 2020 16:05:15
User entered 'No (N)'	System	23 Oct 2020 16:05:15

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:57:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-23T12:03:11', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'd23d8533-cdef-437f-a1d3-a46e752d6300'	System	23 Oct 2020 16:05:15
User entered '23 Oct 2020 12:03'	System	23 Oct 2020 16:05:15

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:57:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:57:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 4'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:57:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-24T13:01:09', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'e8243abb-b900-48e5-a253-802e5db3bf58'	System	24 Oct 2020 17:01:28
User entered 'Yes (Y)'	System	24 Oct 2020 17:01:28

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:57:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-24T13:01:18', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'e8243abb-b900-48e5-a253-802e5db3bf58'	System	24 Oct 2020 17:01:28
User entered '96.9'	System	24 Oct 2020 17:01:28

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-24T13:01:23', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'e8243abb-b900-48e5-a253-802e5db3bf58'	System	24 Oct 2020 17:01:28
User entered 'No (N)'	System	24 Oct 2020 17:01:28

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:57:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-24T13:01:25', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'e8243abb-b900-48e5-a253-802e5db3bf58' User entered '24 Oct 2020 13:01'	System	24 Oct 2020 17:01:28
	System	24 Oct 2020 17:01:28

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:57:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 12:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:57:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 5'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:57:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-25T13:10:17', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '4ac236f2-a1ab-4384-9af0-461e4fadec39'	System	25 Oct 2020 17:11:46
User entered 'Yes (Y)'	System	25 Oct 2020 17:11:46

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:57:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-25T13:11:35', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '4ac236f2-a1ab-4384-9af0-461e4fadec39'	System	25 Oct 2020 17:11:46
User entered '96.2'	System	25 Oct 2020 17:11:46

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-25T13:11:41', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '4ac236f2-a1ab-4384-9af0-461e4fadec39'	System	25 Oct 2020 17:11:46
User entered 'No (N)'	System	25 Oct 2020 17:11:46

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:57:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-25T13:11:44', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '4ac236f2-a1ab-4384-9af0-461e4fadec39' User entered '25 Oct 2020 13:11'	System	25 Oct 2020 17:11:46
	System	25 Oct 2020 17:11:46

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:57:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 12:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:57:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 6'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:57:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-26T16:38:38', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'e6a2cfca-8cc9-41e0-8dcb-044d70608638' User entered 'Yes (Y)'	System	26 Oct 2020 20:38:59
	System	26 Oct 2020 20:38:59

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:57:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-26T16:38:44', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'e6a2cfca-8cc9-41e0-8dcb-044d70608638'	System	26 Oct 2020 20:38:59
User entered '95.9'	System	26 Oct 2020 20:38:59

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-26T16:38:50', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'e6a2cfca-8cc9-41e0-8dcb-044d70608638'	System	26 Oct 2020 20:38:59
User entered 'No (N)'	System	26 Oct 2020 20:38:59

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:57:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-26T16:38:53', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'e6a2cfca-8cc9-41e0-8dcb-044d70608638' User entered '26 Oct 2020 16:38'	System	26 Oct 2020 20:38:59
	System	26 Oct 2020 20:38:59

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:57:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 12:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:57:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 7'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:57:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-27T19:00:22', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f05177ad-2a33-4a18-9a55-cdd223759c54'	System	27 Oct 2020 23:00:56
User entered 'Yes (Y)'	System	27 Oct 2020 23:00:56

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:57:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-27T19:00:42', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f05177ad-2a33-4a18-9a55-cdd223759c54'	System	27 Oct 2020 23:00:56
User entered '97.0'	System	27 Oct 2020 23:00:56

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-27T19:00:49', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f05177ad-2a33-4a18-9a55-cdd223759c54'	System	27 Oct 2020 23:00:56
User entered 'No (N)'	System	27 Oct 2020 23:00:56

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:57:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-27T19:00:52', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f05177ad-2a33-4a18-9a55-cdd223759c54'	System	27 Oct 2020 23:00:56
User entered '27 Oct 2020 19:00'	System	27 Oct 2020 23:00:56

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:57:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 12:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:57:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:57:00

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 (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T16:17:02', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'fb6310eb-996a-49c2-a859-fe42b92db1f3'	System	21 Oct 2020 20:20:08
User entered 'None (1)'	System	21 Oct 2020 20:20:08

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:57:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T16:19:37', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'fb6310eb-996a-49c2-a859-fe42b92db1f3'	System	21 Oct 2020 20:20:08
User entered 'No (N)'	System	21 Oct 2020 20:20:08

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T16:19:42', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'fb6310eb-996a-49c2-a859-fe42b92db1f3'	System	21 Oct 2020 20:20:08
User entered 'No (N)'	System	21 Oct 2020 20:20:08

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:57:00

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 (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T16:19:58', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'fb6310eb-996a-49c2-a859-fe42b92db1f3'	System	21 Oct 2020 20:20:08
User entered 'None (1)'	System	21 Oct 2020 20:20:08

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:57:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T16:20:06', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'fb6310eb-996a-49c2-a859-fe42b92db1f3'	System	21 Oct 2020 20:20:08
User entered '21 Oct 2020 16:20'	System	21 Oct 2020 20:20:08

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:57:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 16:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:57:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 18:30'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 1, after vaccination (at home)'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:57:00

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 (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T20:17:40', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f3f3bdb1-f9c0-4f9f-9cab-42aa08591891'	System	22 Oct 2020 00:18:52
User entered 'None (1)'	System	22 Oct 2020 00:18:52

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:57:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T20:18:02', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f3f3bdb1-f9c0-4f9f-9cab-42aa08591891'	System	22 Oct 2020 00:18:52
User entered 'No (N)'	System	22 Oct 2020 00:18:52

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T20:18:21', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f3f3bdb1-f9c0-4f9f-9cab-42aa08591891'	System	22 Oct 2020 00:18:52
User entered 'No (N)'	System	22 Oct 2020 00:18:52

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:57:00

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 (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T20:18:42', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f3f3bdb1-f9c0-4f9f-9cab-42aa08591891'	System	22 Oct 2020 00:18:52
User entered 'None (1)'	System	22 Oct 2020 00:18:52

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:57:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T20:18:51', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f3f3bdb1-f9c0-4f9f-9cab-42aa08591891'	System	22 Oct 2020 00:18:52
User entered '21 Oct 2020 20:18'	System	22 Oct 2020 00:18:52

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:57:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 19:25'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:57:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 2'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:57:00

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 (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-22T17:12:12', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f4b8c8ec-d6ce-4b39-a8b0-f5b8fd8df1de'	System	22 Oct 2020 21:12:38
User entered 'None (1)'	System	22 Oct 2020 21:12:38

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:57:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-22T17:12:16', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f4b8c8ec-d6ce-4b39-a8b0-f5b8fd8df1de'	System	22 Oct 2020 21:12:38
User entered 'No (N)'	System	22 Oct 2020 21:12:38

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-22T17:12:20', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f4b8c8ec-d6ce-4b39-a8b0-f5b8fd8df1de'	System	22 Oct 2020 21:12:38
User entered 'No (N)'	System	22 Oct 2020 21:12:38

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:57:00

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 (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-22T17:12:29', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f4b8c8ec-d6ce-4b39-a8b0-f5b8fd8df1de'	System	22 Oct 2020 21:12:38
User entered 'None (1)'	System	22 Oct 2020 21:12:38

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:57:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-22T17:12:33', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f4b8c8ec-d6ce-4b39-a8b0-f5b8fd8df1de'	System	22 Oct 2020 21:12:38
User entered '22 Oct 2020 17:12'	System	22 Oct 2020 21:12:38

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:57:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:57:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 3'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:57:00

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 (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-23T12:03:28', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '8e0adcc5-1985-4172-b8bb-82d0f0639a71'	System	23 Oct 2020 16:06:05
User entered 'None (1)'	System	23 Oct 2020 16:06:05

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:57:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-23T12:03:32', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '8e0adcc5-1985-4172-b8bb-82d0f0639a71'	System	23 Oct 2020 16:06:05
User entered 'No (N)'	System	23 Oct 2020 16:06:05

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-23T12:03:38', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '8e0adcc5-1985-4172-b8bb-82d0f0639a71'	System	23 Oct 2020 16:06:05
User entered 'No (N)'	System	23 Oct 2020 16:06:05

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:57:00

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 (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-23T12:03:50', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '8e0adcc5-1985-4172-b8bb-82d0f0639a71' User entered 'None (1)'	System	23 Oct 2020 16:06:05
	System	23 Oct 2020 16:06:05

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:57:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-23T12:03:53', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '8e0adcc5-1985-4172-b8bb-82d0f0639a71' User entered '23 Oct 2020 12:03'	System	23 Oct 2020 16:06:05
	System	23 Oct 2020 16:06:05

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:57:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:57:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 4'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:57:00

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 (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-24T13:01:33', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '5b00e166-f378-43db-b725-3a9ee6703b64'	System	24 Oct 2020 17:01:55
User entered 'None (1)'	System	24 Oct 2020 17:01:55

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:57:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-24T13:01:37', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '5b00e166-f378-43db-b725-3a9ee6703b64'	System	24 Oct 2020 17:01:55
User entered 'No (N)'	System	24 Oct 2020 17:01:55

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-24T13:01:41', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '5b00e166-f378-43db-b725-3a9ee6703b64'	System	24 Oct 2020 17:01:55
User entered 'No (N)'	System	24 Oct 2020 17:01:55

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:57:00

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 (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-24T13:01:49', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '5b00e166-f378-43db-b725-3a9ee6703b64'	System	24 Oct 2020 17:01:55
User entered 'None (1)'	System	24 Oct 2020 17:01:55

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:57:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-24T13:01:53', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '5b00e166-f378-43db-b725-3a9ee6703b64' User entered '24 Oct 2020 13:01'	System	24 Oct 2020 17:01:55
	System	24 Oct 2020 17:01:55

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:57:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 12:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:57:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 5'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:57:00

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 (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-25T13:11:49', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f697aef2-220e-469f-b89a-c62ae3183a3c' User entered 'None (1)'	System	25 Oct 2020 17:12:15
	System	25 Oct 2020 17:12:15

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:57:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-25T13:11:52', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f697aef2-220e-469f-b89a-c62ae3183a3c'	System	25 Oct 2020 17:12:15
User entered 'No (N)'	System	25 Oct 2020 17:12:15

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-25T13:11:55', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f697aef2-220e-469f-b89a-c62ae3183a3c' User entered 'No (N)'	System	25 Oct 2020 17:12:15

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:57:00

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 (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-25T13:12:07', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f697aef2-220e-469f-b89a-c62ae3183a3c'	System	25 Oct 2020 17:12:15
User entered 'None (1)'	System	25 Oct 2020 17:12:15

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:57:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-25T13:12:10', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f697aef2-220e-469f-b89a-c62ae3183a3c' User entered '25 Oct 2020 13:12'	System	25 Oct 2020 17:12:15
	System	25 Oct 2020 17:12:15

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:57:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 12:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:57:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 6'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:57:00

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 (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-26T16:38:58', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '7193c7e7-c504-486e-bfab-af082d7586f8'	System	26 Oct 2020 20:39:15
User entered 'None (1)'	System	26 Oct 2020 20:39:15

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:57:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-26T16:39:04', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '7193c7e7-c504-486e-bfab-af082d7586f8'	System	26 Oct 2020 20:39:15
User entered 'No (N)'	System	26 Oct 2020 20:39:15

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-26T16:39:08', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '7193c7e7-c504-486e-bfab-af082d7586f8' User entered 'No (N)'	System	26 Oct 2020 20:39:15

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:57:00

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 (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-26T16:39:10', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '7193c7e7-c504-486e-bfab-af082d7586f8'	System	26 Oct 2020 20:39:15
User entered 'None (1)'	System	26 Oct 2020 20:39:15

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:57:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-26T16:39:13', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '7193c7e7-c504-486e-bfab-af082d7586f8' User entered '26 Oct 2020 16:39'	System	26 Oct 2020 20:39:15
	System	26 Oct 2020 20:39:15

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:57:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 12:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:57:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 7'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:57:00

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 (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-27T19:00:55', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'bb15805a-08a9-4a65-90ac-a1ed352f9d0f' User entered 'None (1)'	System	27 Oct 2020 23:01:22

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:57:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-27T19:01:09', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'bb15805a-08a9-4a65-90ac-a1ed352f9d0f'	System	27 Oct 2020 23:01:22
User entered 'No (N)'	System	27 Oct 2020 23:01:22

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-27T19:01:15', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'bb15805a-08a9-4a65-90ac-a1ed352f9d0f'	System	27 Oct 2020 23:01:22
User entered 'No (N)'	System	27 Oct 2020 23:01:22

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:57:00

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 (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-27T19:01:18', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'bb15805a-08a9-4a65-90ac-a1ed352f9d0f' User entered 'None (1)'	System	27 Oct 2020 23:01:22
	System	27 Oct 2020 23:01:22

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:57:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-27T19:01:20', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'bb15805a-08a9-4a65-90ac-a1ed352f9d0f' User entered '27 Oct 2020 19:01'	System	27 Oct 2020 23:01:22
	System	27 Oct 2020 23:01:22

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:57:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 12:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:57:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:57:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T16:20:17', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'c8633421-fc51-46af-a62b-b333255a80c8' User entered 'None (0)'	System	21 Oct 2020 20:21:10
	System	21 Oct 2020 20:21:10

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:57:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T16:20:24', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'c8633421-fc51-46af-a62b-b333255a80c8' User entered 'None (0)'	System	21 Oct 2020 20:21:10
	System	21 Oct 2020 20:21:10

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:57:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T16:20:33', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'c8633421-fc51-46af-a62b-b333255a80c8' User entered 'None (0)'	System	21 Oct 2020 20:21:10
	System	21 Oct 2020 20:21:10

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:57:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T16:20:41', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'c8633421-fc51-46af-a62b-b333255a80c8' User entered 'None (0)'	System	21 Oct 2020 20:21:10
	System	21 Oct 2020 20:21:10

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:57:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T16:20:45', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'c8633421-fc51-46af-a62b-b333255a80c8' User entered 'None (0)'	System	21 Oct 2020 20:21:10
	System	21 Oct 2020 20:21:10

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:57:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T16:20:51', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'c8633421-fc51-46af-a62b-b333255a80c8'	System	21 Oct 2020 20:21:10
User entered 'None (0)'	System	21 Oct 2020 20:21:10

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:57:00

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 (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T16:21:02', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'c8633421-fc51-46af-a62b-b333255a80c8'	System	21 Oct 2020 20:21:10
User entered 'No (N)'	System	21 Oct 2020 20:21:10

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:57:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T16:21:09', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'c8633421-fc51-46af-a62b-b333255a80c8' User entered '21 Oct 2020 16:21'	System	21 Oct 2020 20:21:10
	System	21 Oct 2020 20:21:10

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:57:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 16:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:57:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 18:30'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 1, after vaccination (at home)'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:57:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T20:19:02', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '90ee672b-956e-4c33-98d2-bfb1ca7363fd'	System	22 Oct 2020 00:19:40
User entered 'None (0)'	System	22 Oct 2020 00:19:40

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:57:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T20:19:06', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '90ee672b-956e-4c33-98d2-bfb1ca7363fd'	System	22 Oct 2020 00:19:40
User entered 'None (0)'	System	22 Oct 2020 00:19:40

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:57:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T20:19:10', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '90ee672b-956e-4c33-98d2-bfb1ca7363fd'	System	22 Oct 2020 00:19:40
User entered 'None (0)'	System	22 Oct 2020 00:19:40

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:57:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T20:19:14', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '90ee672b-956e-4c33-98d2-bfb1ca7363fd' User entered 'None (0)'	System	22 Oct 2020 00:19:40

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:57:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T20:19:17', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '90ee672b-956e-4c33-98d2-bfb1ca7363fd' User entered 'None (0)'	System	22 Oct 2020 00:19:40
	System	22 Oct 2020 00:19:40

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:57:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T20:19:20', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '90ee672b-956e-4c33-98d2-bfb1ca7363fd' User entered 'None (0)'	System	22 Oct 2020 00:19:40
	System	22 Oct 2020 00:19:40

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:57:00

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 (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T20:19:32', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '90ee672b-956e-4c33-98d2-bfb1ca7363fd'	System	22 Oct 2020 00:19:40
User entered 'No (N)'	System	22 Oct 2020 00:19:40

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:57:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T20:19:38', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '90ee672b-956e-4c33-98d2-bfb1ca7363fd' User entered '21 Oct 2020 20:19'	System	22 Oct 2020 00:19:40
	System	22 Oct 2020 00:19:40

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:57:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 19:25'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:57:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:57:00

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 2'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:57:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-22T17:12:40', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '40b51bdf-2d30-42f1-9bcc-f283c8d987d4'	System	22 Oct 2020 21:13:14
User entered 'None (0)'	System	22 Oct 2020 21:13:14

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:57:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-22T17:12:46', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '40b51bdf-2d30-42f1-9bcc-f283c8d987d4'	System	22 Oct 2020 21:13:14
User entered 'None (0)'	System	22 Oct 2020 21:13:14

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:57:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-22T17:12:51', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '40b51bdf-2d30-42f1-9bcc-f283c8d987d4'	System	22 Oct 2020 21:13:14
User entered 'None (0)'	System	22 Oct 2020 21:13:14

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:57:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-22T17:12:55', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '40b51bdf-2d30-42f1-9bcc-f283c8d987d4'	System	22 Oct 2020 21:13:14
User entered 'None (0)'	System	22 Oct 2020 21:13:14

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:57:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-22T17:12:59', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '40b51bdf-2d30-42f1-9bcc-f283c8d987d4'	System	22 Oct 2020 21:13:14
User entered 'None (0)'	System	22 Oct 2020 21:13:14

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:57:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-22T17:13:03', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '40b51bdf-2d30-42f1-9bcc-f283c8d987d4'	System	22 Oct 2020 21:13:14
User entered 'None (0)'	System	22 Oct 2020 21:13:14

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:57:00

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 (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-22T17:13:08', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '40b51bdf-2d30-42f1-9bcc-f283c8d987d4'	System	22 Oct 2020 21:13:14
User entered 'No (N)'	System	22 Oct 2020 21:13:14

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:57:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-22T17:13:11', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '40b51bdf-2d30-42f1-9bcc-f283c8d987d4'	System	22 Oct 2020 21:13:14
User entered '22 Oct 2020 17:13'	System	22 Oct 2020 21:13:14

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:57:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:57:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:57:00

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 3'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:57:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-23T12:04:03', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '973e7226-6311-47c2-9798-f7238ee72ae2'	System	23 Oct 2020 16:06:49
User entered 'None (0)'	System	23 Oct 2020 16:06:49

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:57:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-23T12:04:08', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '973e7226-6311-47c2-9798-f7238ee72ae2' User entered 'None (0)'	System	23 Oct 2020 16:06:49
	System	23 Oct 2020 16:06:49

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:57:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-23T12:04:14', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '973e7226-6311-47c2-9798-f7238ee72ae2' User entered 'None (0)'	System	23 Oct 2020 16:06:49
	System	23 Oct 2020 16:06:49

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:57:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-23T12:04:20', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '973e7226-6311-47c2-9798-f7238ee72ae2'	System	23 Oct 2020 16:06:49
User entered 'None (0)'	System	23 Oct 2020 16:06:49

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:57:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-23T12:04:22', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '973e7226-6311-47c2-9798-f7238ee72ae2'	System	23 Oct 2020 16:06:49
User entered 'None (0)'	System	23 Oct 2020 16:06:49

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:57:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-23T12:04:25', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '973e7226-6311-47c2-9798-f7238ee72ae2'	System	23 Oct 2020 16:06:49
User entered 'None (0)'	System	23 Oct 2020 16:06:49

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:57:00

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 (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-23T12:04:30', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '973e7226-6311-47c2-9798-f7238ee72ae2'	System	23 Oct 2020 16:06:49
User entered 'No (N)'	System	23 Oct 2020 16:06:49

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:57:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-23T12:04:33', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '973e7226-6311-47c2-9798-f7238ee72ae2' User entered '23 Oct 2020 12:04'	System	23 Oct 2020 16:06:49
	System	23 Oct 2020 16:06:49

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:57:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:57:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 4'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:57:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-24T13:02:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'a282b5b0-1ae4-4295-9571-25509a4d4a09'	System	24 Oct 2020 17:02:24
User entered 'None (0)'	System	24 Oct 2020 17:02:24

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:57:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-24T13:02:06', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'a282b5b0-1ae4-4295-9571-25509a4d4a09'	System	24 Oct 2020 17:02:24
User entered 'None (0)'	System	24 Oct 2020 17:02:24

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:57:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-24T13:02:09', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'a282b5b0-1ae4-4295-9571-25509a4d4a09'	System	24 Oct 2020 17:02:24
User entered 'None (0)'	System	24 Oct 2020 17:02:24

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:57:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-24T13:02:10', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'a282b5b0-1ae4-4295-9571-25509a4d4a09'	System	24 Oct 2020 17:02:24
User entered 'None (0)'	System	24 Oct 2020 17:02:24

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:57:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-24T13:02:12', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'a282b5b0-1ae4-4295-9571-25509a4d4a09'	System	24 Oct 2020 17:02:24
User entered 'None (0)'	System	24 Oct 2020 17:02:24

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:57:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-24T13:02:14', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'a282b5b0-1ae4-4295-9571-25509a4d4a09'	System	24 Oct 2020 17:02:24
User entered 'None (0)'	System	24 Oct 2020 17:02:24

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:57:00

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 (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-24T13:02:20', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'a282b5b0-1ae4-4295-9571-25509a4d4a09'	System	24 Oct 2020 17:02:24
User entered 'No (N)'	System	24 Oct 2020 17:02:24

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:57:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-24T13:02:22', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'a282b5b0-1ae4-4295-9571-25509a4d4a09' User entered '24 Oct 2020 13:02'	System	24 Oct 2020 17:02:24
	System	24 Oct 2020 17:02:24

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:57:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 12:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:57:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:57:00

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 5'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:57:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-25T13:12:20', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '5d91caa0-06e7-40a0-9bca-014c5c61dda8'	System	25 Oct 2020 17:12:46
User entered 'None (0)'	System	25 Oct 2020 17:12:46

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:57:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-25T13:12:22', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '5d91caa0-06e7-40a0-9bca-014c5c61dda8' User entered 'None (0)'	System	25 Oct 2020 17:12:46
	System	25 Oct 2020 17:12:46

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:57:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-25T13:12:26', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '5d91caa0-06e7-40a0-9bca-014c5c61dda8'	System	25 Oct 2020 17:12:46
User entered 'None (0)'	System	25 Oct 2020 17:12:46

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:57:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-25T13:12:29', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '5d91caa0-06e7-40a0-9bca-014c5c61dda8' User entered 'None (0)'	System	25 Oct 2020 17:12:46
	System	25 Oct 2020 17:12:46

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:57:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-25T13:12:32', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '5d91caa0-06e7-40a0-9bca-014c5c61dda8'	System	25 Oct 2020 17:12:46
User entered 'None (0)'	System	25 Oct 2020 17:12:46

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:57:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-25T13:12:37', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '5d91caa0-06e7-40a0-9bca-014c5c61dda8' User entered 'None (0)'	System	25 Oct 2020 17:12:46
	System	25 Oct 2020 17:12:46

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:57:00

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 (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-25T13:12:40', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '5d91caa0-06e7-40a0-9bca-014c5c61dda8'	System	25 Oct 2020 17:12:46
User entered 'No (N)'	System	25 Oct 2020 17:12:46

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:57:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-25T13:12:43', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '5d91caa0-06e7-40a0-9bca-014c5c61dda8' User entered '25 Oct 2020 13:12'	System	25 Oct 2020 17:12:46
	System	25 Oct 2020 17:12:46

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:57:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 12:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:57:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:57:00

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 6'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:57:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-26T16:39:16', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '1672818e-71a0-426b-ba84-e4ac992201d3'	System	26 Oct 2020 20:39:33
User entered 'None (0)'	System	26 Oct 2020 20:39:33

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:57:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-26T16:39:17', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '1672818e-71a0-426b-ba84-e4ac992201d3'	System	26 Oct 2020 20:39:33
User entered 'None (0)'	System	26 Oct 2020 20:39:33

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:57:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-26T16:39:19', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '1672818e-71a0-426b-ba84-e4ac992201d3'	System	26 Oct 2020 20:39:33
User entered 'None (0)'	System	26 Oct 2020 20:39:33

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:57:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-26T16:39:22', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '1672818e-71a0-426b-ba84-e4ac992201d3'	System	26 Oct 2020 20:39:33
User entered 'None (0)'	System	26 Oct 2020 20:39:33

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:57:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-26T16:39:24', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '1672818e-71a0-426b-ba84-e4ac992201d3'	System	26 Oct 2020 20:39:33
User entered 'None (0)'	System	26 Oct 2020 20:39:33

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:57:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-26T16:39:26', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '1672818e-71a0-426b-ba84-e4ac992201d3'	System	26 Oct 2020 20:39:33
User entered 'None (0)'	System	26 Oct 2020 20:39:33

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:57:00

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 (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-26T16:39:28', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '1672818e-71a0-426b-ba84-e4ac992201d3'	System	26 Oct 2020 20:39:33
User entered 'No (N)'	System	26 Oct 2020 20:39:33

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:57:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-26T16:39:30', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '1672818e-71a0-426b-ba84-e4ac992201d3'	System	26 Oct 2020 20:39:33
User entered '26 Oct 2020 16:39'	System	26 Oct 2020 20:39:33

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:57:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 12:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:57:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 7'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:57:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-27T19:01:25', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'd78f557a-8956-48c6-80d7-05193bce9c27'	System	27 Oct 2020 23:02:15
User entered 'None (0)'	System	27 Oct 2020 23:02:15

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:57:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-27T19:01:27', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'd78f557a-8956-48c6-80d7-05193bce9c27'	System	27 Oct 2020 23:02:15
User entered 'None (0)'	System	27 Oct 2020 23:02:15

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:57:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-27T19:01:29', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'd78f557a-8956-48c6-80d7-05193bce9c27'	System	27 Oct 2020 23:02:15
User entered 'None (0)'	System	27 Oct 2020 23:02:15

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:57:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-27T19:01:31', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'd78f557a-8956-48c6-80d7-05193bce9c27'	System	27 Oct 2020 23:02:15
User entered 'None (0)'	System	27 Oct 2020 23:02:15

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:57:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-27T19:01:33', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'd78f557a-8956-48c6-80d7-05193bce9c27'	System	27 Oct 2020 23:02:15
User entered 'None (0)'	System	27 Oct 2020 23:02:15

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:57:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-27T19:01:35', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'd78f557a-8956-48c6-80d7-05193bce9c27'	System	27 Oct 2020 23:02:15
User entered 'None (0)'	System	27 Oct 2020 23:02:15

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:57:00

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 (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-27T19:02:08', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'd78f557a-8956-48c6-80d7-05193bce9c27'	System	27 Oct 2020 23:02:15
User entered 'No (N)'	System	27 Oct 2020 23:02:15

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:57:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-27T19:02:10', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'd78f557a-8956-48c6-80d7-05193bce9c27'	System	27 Oct 2020 23:02:15
User entered '27 Oct 2020 19:02'	System	27 Oct 2020 23:02:15

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:57:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 12:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:57:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:57:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	29 Oct 2020 21:36:22

US3842060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '29 Oct 2020'	Christie Lyn Costanza (b) (4)	29 Oct 2020 21:36:22

US3842060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Christie Lyn Costanza (b) (4)	29 Oct 2020 21:36:22

US3842060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:57:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Christie Lyn Costanza (b) (4)	29 Oct 2020 21:36:22

US3842060

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	29 Oct 2020 21:36:25

US3842060

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:57:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 21:36:25

US3842060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:57:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:21:13

US3842060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '7 Nov 2020'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:21:13

US3842060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:21:13

US3842060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:57:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:21:13

US3842060

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:21:04

US3842060

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:57:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 20:21:04

US3842060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:57:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:21:43

US3842060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '13 Nov 2020'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:21:43

US3842060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:21:43

US3842060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:57:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:21:43

US3842060

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:21:47

US3842060

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:57:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 20:21:47

US3842060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:57:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:22:00

US3842060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '18 Nov 2020'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:22:00

US3842060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:22:00

US3842060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:57:00

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	18 Nov 2020 20:22:00

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:57:00

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:57:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:57:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Nov 2020'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '14:21'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '18 Nov 2020 14:21'	System	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:57:00

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.1' F	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:57:00

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:57:00

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:57:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '74'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:57:00

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '16'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:57:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:57:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '114'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:57:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:57:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '75'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:57:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:57:00

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:57:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:57:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:57:00

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:57:00

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:57:00

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:57:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:57:00

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:57:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:57:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:57:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:57:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:57:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:57:00

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:22:07

US3842060

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:57:00

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:22:07

US3842060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:57:00

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:22:38

US3842060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:57:00

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:22:38

US3842060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered 'PROTOCOL DIRECTIVE VIA EPIP HAS REQUESTED THAT 2ND DOSE NOT BE ADMINISTERED. PARTICIPANT HAD A POSITIVE SALIVA TEST THAT WAS ADMINISTERED AT HIS WORKSITE.' reason for change: Data Entry Error	Malithi Desilva (b) (4)	18 Nov 2020 20:23:13
User entered empty.	Malithi Desilva (b) (4)	18 Nov 2020 20:22:38

US3842060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:57:00

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:22:38

US3842060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:57:00

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:22:38

US3842060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:22:38

US3842060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:22:38

US3842060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:22:38

US3842060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:22:38

US3842060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:22:38

US3842060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:57:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mario Portilla (b) (4)	18 Nov 2020 20:54:38

US3842060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:57:00

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '18 Nov 2020'	Mario Portilla (b) (4)	18 Nov 2020 20:54:38

US3842060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:57:00

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Nov 2020 20:57:12
User entered '14:40' reason for change: Data Entry Error	Mario Portilla (b) (4)	18 Nov 2020 20:57:12
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Nov 2020 20:54:38
User entered empty.	Mario Portilla (b) (4)	18 Nov 2020 20:54:38

US3842060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '18 Nov 2020 14:40'	System	18 Nov 2020 20:57:12
User entered empty.	System	18 Nov 2020 20:54:38

US3842060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:57:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Nov 2020'	Mario Portilla (b) (4)	18 Nov 2020 20:56:02

US3842060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:57:00

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mario Portilla (b) (4)	18 Nov 2020 20:56:02

US3842060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:57:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mario Portilla (b) (4)	18 Nov 2020 20:56:02

US3842060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:57:00

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	18 Nov 2020 20:56:46
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	18 Nov 2020 20:56:46
User entered '14:42' reason for change: Data Entry Error	Mario Portilla (b) (4) [REDACTED]	18 Nov 2020 20:56:46
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	18 Nov 2020 20:56:02
User entered empty.	Mario Portilla (b) (4) [REDACTED]	18 Nov 2020 20:56:02

US3842060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '18 Nov 2020 14:42'	System	18 Nov 2020 20:56:46
User entered empty.	System	18 Nov 2020 20:56:02

US3842060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:57:00

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mario Portilla (b) (4)	18 Nov 2020 20:56:02

US3842060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:57:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 20:56:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Nov 2020 20:56:53
User entered 'No (N)' reason for change: Data Entry Error	Mario Portilla (b) (4)	18 Nov 2020 20:56:53
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 20:56:02
User entered empty.	Mario Portilla (b) (4)	18 Nov 2020 20:56:02

US3842060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:57:00

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Mario Portilla (b) (4)	18 Nov 2020 20:56:02

US3842060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 20:56:02

US3842060

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:23:29

US3842060

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:57:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 20:23:29

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '18 Nov 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '22 Nov 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '25 Nov 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '29 Nov 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '02 Dec 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '06 Dec 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '09 Dec 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '13 Dec 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '16 Dec 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '20 Dec 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '23 Dec 2022 00:01'	System	20 Nov 2020 13:21:55

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:57:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '27 Dec 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: Covid-19 Assessment 29 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:57:00

[Date of Contact](#)

Audit	User	Time (GMT)
User entered '29 Oct 2020'	Zoraida Cruz (b) (4) (b) (4)	23 Nov 2020 18:34:44

US3842060

Folder: Covid-19 Assessment 29 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:57:00

[Time of Contact](#)

Audit	User	Time (GMT)
User entered '03:46'	Zoraida Cruz (b) (4) (b) (4)	23 Nov 2020 18:34:44

US3842060

Folder: Covid-19 Assessment 29 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:57:00

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Oct 2020 03:46'	System	23 Nov 2020 18:34:44

US3842060

Folder: Covid-19 Assessment 29 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:57:00

[Type of Contact](#)

Audit	User	Time (GMT)
User entered 'Safety Call (Safety Call)'	Zoraida Cruz (b) (4) (b) (4)	23 Nov 2020 18:34:44

US3842060

Folder: Covid-19 Assessment 29 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:57:00

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Zoraida Cruz (b) (4) (b) (4)	23 Nov 2020 18:34:44

US3842060

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:57:00

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Mario Portilla (b) (4)	29 Oct 2020 22:13:25
User entered 'No (N)'	Mario Portilla (b) (4)	29 Oct 2020 22:13:01

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please review the condition and confirm. As per CCG (page 34), until the diagnosis is not confirmed COVID-19, the same should not be recorded at AE page.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 14:03:00
User closed query 'Per CDM: per sponsor review, Please consider changing AE name to Covid-19' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 13:59:40
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Asymptomatic COVID-19, LLT: Asymptomatic COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 21:57:59
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 21:57:59
Query 'Per CDM: Please review the condition and confirm. As per CCG (page 34), until the diagnosis is not confirmed COVID-19, the same should not be recorded at AE page.' answered with 'error corrected.' (Site from DM).	Zoraida Cruz (b) (4) (b) (4)	23 Nov 2020 19:03:18
Query 'Per CDM: per sponsor review, Please consider changing AE name to Covid-19' answered with 'Error corrected AE name per query.' (Site from DM).	Zoraida Cruz (b) (4) (b) (4)	23 Nov 2020 18:38:19
Data point term sent to Coder	System	23 Nov 2020 18:37:55
Coding entries removed.	Zoraida Cruz (b) (4) (b) (4)	23 Nov 2020 18:37:35
User entered 'A-Symptomatic Covid-19' reason for change: Per Query Resolution	Zoraida Cruz (b) (4) (b) (4)	23 Nov 2020 18:37:35
User opened query 'Per CDM: Please review the condition and confirm. As per CCG (page 34), until the diagnosis is not confirmed COVID-19, the same should not be recorded at AE page.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 08:17:25
User opened query 'Per CDM: per sponsor review, Please consider changing AE name to Covid-19' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 13:38:50
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 13:38:43

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'Participant assessed for COVID 19 symptoms 02NOV. Participant denies any symptoms to date. Resulted as not detected on 03NOV' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 19:52:59
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	17 Nov 2020 14:04:01
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Asymptomatic COVID-19, LLT: Asymptomatic COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 23:28:54
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 23:28:54
Data point term sent to Coder	System	29 Oct 2020 22:27:43
User entered 'Asymptomatic COVID-19 reported by participant. Job requires weekly testing (saliva test) which was completed on Monday 10/26/2020 and results were reported to 2060 this date.'	Mario Portilla (b) (4) (b) (4)	29 Oct 2020 22:27:10

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '26 Oct 2020' reason for change: Data Entry Error	Zoraida Cruz (b) (4)	23 Nov 2020 19:02:59
User entered '28 Oct 2020'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	29 Oct 2020 22:29:12
User entered empty; reason for change Data Entry Error	Mario Portilla (b) (4) [REDACTED]	29 Oct 2020 22:29:12
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	29 Oct 2020 22:27:10
User entered '15:22'	Mario Portilla (b) (4) [REDACTED]	29 Oct 2020 22:27:10

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 22:29:12
User entered '28 Oct 2020 15:22'	System	29 Oct 2020 22:27:10

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	19 Nov 2020 19:21:20
User entered 'No (N)' reason for change: Data Entry Error	Mario Portilla (b) (4) [REDACTED]	19 Nov 2020 19:21:20
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	19 Nov 2020 19:20:57
User entered 'Yes (Y)'	Mario Portilla (b) (4) [REDACTED]	29 Oct 2020 22:27:10

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '26 Oct 2020' reason for change: Data Entry Error	Zoraida Cruz (b) (4)	23 Nov 2020 19:02:59
User entered '29 Oct 2020' reason for change: Data Entry Error	Mario Portilla (b) (4)	19 Nov 2020 19:20:57
User entered empty.	Mario Portilla (b) (4)	29 Oct 2020 22:27:10

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered empty.	Mario Portilla (b) (4)	29 Oct 2020 22:27:10

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 22:27:10

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Mario Portilla (b) (4)	29 Oct 2020 22:27:10

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Mario Portilla (b) (4)	29 Oct 2020 22:27:10

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Mario Portilla (b) (4)	29 Oct 2020 22:27:10

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Mario Portilla (b) (4)	29 Oct 2020 22:27:10

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 14:01:30
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'The primary reason for discontinuation participant testing positive on a local test. per PPD even if asymptomatic should not receive the 2nd dose as it would be contraindicated per protocol.' (Site from System).	Zoraida Cruz (b) (4)	23 Nov 2020 19:09:14
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	23 Nov 2020 19:02:59
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Zoraida Cruz (b) (4)	23 Nov 2020 19:02:59
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Oct 2020 22:29:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Oct 2020 22:29:12
User entered 'None (NONE)' reason for change: Data Entry Error	Mario Portilla (b) (4)	29 Oct 2020 22:29:12
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Oct 2020 22:27:10
User entered empty.	Mario Portilla (b) (4)	29 Oct 2020 22:27:10

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

[None](#)

Audit	User	Time (GMT)
User entered '1'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Mario Portilla (b) (4) [REDACTED]	19 Nov 2020 19:20:57
User entered 'Unknown (UNKNOWN)'	Mario Portilla (b) (4) [REDACTED] [REDACTED]	29 Oct 2020 22:27:10

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Mario Portilla (b) (4)	29 Oct 2020 22:27:10

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Participant positive on local saliva test, Zoraida Cruz reported A-symptomatic. Confirmed with PPD, per protocol participant discontinued from receiving study product. Will continue study schedules and procedures.' reason for change: Data Entry Error	(b) (4)	23 Nov 2020 19:02:59
User entered 'Participant will come to site for NP test. PMD will be notified per participant's consent in enrollment.	Mario Portilla (b) (4)	29 Oct 2020 22:27:10
(b) (6)		
VISIT #2 is scheduled for Wednesday 18Nov2020. Pending outcome of confirmatory testing, site to follow protocol guidelines'		

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	29 Oct 2020 22:27:10

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:57:00

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Oct 2020 22:27:10

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 19:32:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	19 Nov 2020 19:32:13
Data point term sent to Coder	System	19 Nov 2020 19:31:53
User entered 'Anxiety'	Mario Portilla (b) (4)	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mario Portilla (b) (4)	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mario Portilla (b) (4)	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mario Portilla (b) (4)	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '17 Nov 2020'	Mario Portilla (b) (4)	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered empty.	Mario Portilla (b) (4)	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mario Portilla (b) (4)	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '17 Nov 2020'	Mario Portilla (b) (4)	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered empty.	Mario Portilla (b) (4)	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mario Portilla (b) (4)	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mario Portilla (b) (4)	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Mario Portilla (b) (4)	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Mario Portilla (b) (4)	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Mario Portilla (b) (4)	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Mario Portilla (b) (4)	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Mario Portilla (b) (4)	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Mario Portilla (b) (4)	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Mario Portilla (b) (4)	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Mario Portilla (b) (4)	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Mario Portilla (b) (4)	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Mario Portilla (b) (4)	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Mario Portilla (b) (4)	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Mario Portilla (b) (4)	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 19:13:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Nov 2020 19:13:03
User entered 'None (NONE)' reason for change: Data Entry Error	Zoraida Cruz (b) (4) (b) (4)	23 Nov 2020 19:13:03
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 19:31:03
User entered empty.	Mario Portilla (b) (4) [REDACTED] [REDACTED]	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

[None](#)

Audit	User	Time (GMT)
User entered '0'	Mario Portilla (b) (4)	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Mario Portilla (b) (4)	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Mario Portilla (b) (4)	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mario Portilla (b) (4)	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Mario Portilla (b) (4)	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Anxiety related to MRI induced claustrophobia'	Mario Portilla (b) (4) [REDACTED]	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:57:00

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Fear symptoms and phobic disorders (incl social phobia), PT: Claustrophobia, LLT: Claustrophobia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 19:36:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 19:36:01
Data point term sent to Coder	System	19 Nov 2020 19:34:59
User entered 'Claustrophobia'	Mario Portilla (b) (4) (b) (4) (b) (4)	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mario Portilla (b) (4)	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mario Portilla (b) (4)	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mario Portilla (b) (4)	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '17 Nov 2020'	Mario Portilla (b) (4)	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered empty.	Mario Portilla (b) (4)	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mario Portilla (b) (4)	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '17 Nov 2020'	Mario Portilla (b) (4)	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered empty.	Mario Portilla (b) (4)	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mario Portilla (b) (4)	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mario Portilla (b) (4)	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Mario Portilla (b) (4)	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Mario Portilla (b) (4)	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Mario Portilla (b) (4)	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Mario Portilla (b) (4)	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Mario Portilla (b) (4)	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Mario Portilla (b) (4)	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Mario Portilla (b) (4)	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Mario Portilla (b) (4)	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Mario Portilla (b) (4)	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Mario Portilla (b) (4)	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Mario Portilla (b) (4)	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Mario Portilla (b) (4)	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Mario Portilla (b) (4)	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

[None](#)

Audit	User	Time (GMT)
User entered '0'	Mario Portilla (b) (4)	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Mario Portilla (b) (4)	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Mario Portilla (b) (4)	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mario Portilla (b) (4) [REDACTED]	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Mario Portilla (b) (4)	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Claustrophobia induced by MRI'	Mario Portilla (b) (4)	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:57:00

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 19:34:45

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:57:00

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:32:52

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:57:00

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 05:02:28
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 05:02:28
Data point term sent to Coder	System	21 Oct 2020 19:36:27
User entered 'Simvastatin'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:36:16

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:57:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:36:16

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:57:00

[Indication](#)

Audit	User	Time (GMT)
User entered 'Reduce Risk of MI or Brain Attack'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:36:16

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:57:00

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:36:16

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:57:00

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:36:16

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:57:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:36:16

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:57:00

[Frequency](#)

Audit	User	Time (GMT)
User entered 'other (OTHER)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:36:16

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:57:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered 'occasional'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:36:16

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:57:00

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:36:16

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:57:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:36:16

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:36:16

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:57:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:36:16

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:57:00

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:36:16

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:57:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:36:16

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:57:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:36:16

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:57:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 19:36:16

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:57:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 19:36:16

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:57:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 19:36:16

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:57:00

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 19:49:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 19:49:34
Data point term sent to Coder	System	21 Oct 2020 19:48:49
User entered 'Vitamin B12'	Zoraida Cruz (b) (4)	21 Oct 2020 19:48:18

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:57:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:48:18

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:57:00

[Indication](#)

Audit	User	Time (GMT)
User entered 'Nutritional Supplement'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:48:18

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:57:00

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:48:18

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:57:00

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'tablet (TABLET)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:48:18

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:57:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:48:18

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:57:00

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:48:18

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:57:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:48:18

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:57:00

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:48:18

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:57:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:48:18

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2016'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:48:18

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:57:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:48:18

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:57:00

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:48:18

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:57:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:48:18

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:57:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:48:18

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:57:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 19:48:18

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:57:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 19:48:18

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:57:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 19:48:18

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:57:00

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: DIAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 22:24:48
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 22:24:48
Data point term sent to Coder	System	19 Nov 2020 19:15:16
Data point term sent to Coder	System	19 Nov 2020 19:11:07
User entered 'diazepam'	Mario Portilla (b) (4)	19 Nov 2020 19:10:56

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:57:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mario Portilla (b) (4)	19 Nov 2020 19:10:56

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:57:00

[Indication](#)

Audit	User	Time (GMT)
User entered 'ANXIETY RELATED TO MRI induced claustrophobia' reason for change: Data Entry Error	Mario Portilla (b) (4)	19 Nov 2020 19:14:51
User entered 'anxiety related to claustrophobia in MRI'	Mario Portilla (b) (4)	19 Nov 2020 19:10:56

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:57:00

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '25'	Mario Portilla (b) (4)	19 Nov 2020 19:10:56

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:57:00

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Mario Portilla (b) (4)	19 Nov 2020 19:10:56

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:57:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Mario Portilla (b) (4)	19 Nov 2020 19:10:56

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:57:00

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Mario Portilla (b) (4)	19 Nov 2020 19:10:56

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:57:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Mario Portilla (b) (4)	19 Nov 2020 19:10:56

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:57:00

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Mario Portilla (b) (4)	19 Nov 2020 19:10:56

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:57:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Mario Portilla (b) (4)	19 Nov 2020 19:10:56

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:57:00

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

Audit	User	Time (GMT)
User entered '17 Nov 2020'	Mario Portilla (b) (4)	19 Nov 2020 19:10:56

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:57:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Mario Portilla (b) (4)	19 Nov 2020 19:10:56

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:57:00

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mario Portilla (b) (4)	19 Nov 2020 19:10:56

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:57:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '17 Nov 2020'	Mario Portilla (b) (4)	19 Nov 2020 19:10:56

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:57:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mario Portilla (b) (4)	19 Nov 2020 19:10:56

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:57:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Nov 2020 19:10:56

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:57:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 19:10:56

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:57:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 19:10:56

US3842060

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:57:00

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per CDM re-query: Site response is noted; however, Visit 1 Day 1 Exposure was on 21Oct2020. Please confirm and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 14:10:00
User closed query 'Per CDM: Per pages 38-39 of CCGs version 2.0, "Date of dosing discontinuation" should be the same as date of last exposure. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 14:10:00
Query 'Per CDM: Per pages 38-39 of CCGs version 2.0, "Date of dosing discontinuation" should be the same as date of last exposure. Thank you.' answered with 'The participant reported testing positive on a saliva test conducted in the workplace on 26OCT2020' (Site from DM).	Zoraida Cruz (b) (4) (b) (4)	23 Nov 2020 18:04:13
User entered '26 Oct 2020' reason for change: Data Entry Error	Zoraida Cruz (b) (4) (b) (4)	23 Nov 2020 18:02:57
User opened query 'Per CDM: Per pages 38-39 of CCGs version 2.0, "Date of dosing discontinuation" should be the same as date of last exposure. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 15:00:07
User entered '18 Nov 2020'	Mario Portilla (b) (4)	18 Nov 2020 20:02:07

US3842060

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:57:00

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User entered 'Due to SARS-COV-2 (COVID)'	Zoraida Cruz (b) (4)	23 Nov 2020 18:04:51
reason for change: Data Entry Error	(b) (4)	
User entered 'Other (OTHER)'	Mario Portilla (b) (4)	18 Nov 2020 20:02:07

US3842060

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:57:00

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCGs pages 38-39 of CCGs version 2.0 (enter due to SARS-COV-2 if participant is diagnosed). Please confirm if patient was diagnosed. Also complete the Covid-19 Assessment and AE pages. Thank you. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 14:03:52
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	23 Nov 2020 18:07:18
User entered empty; reason for change Per Query Resolution	Zoraida Cruz (b) (4)	23 Nov 2020 18:07:18
Query 'Per CDM: Per CCGs pages 38-39 of CCGs version 2.0 (enter due to SARS-COV-2 if participant is diagnosed). Please confirm if patient was diagnosed. Also complete the Covid-19 Assessment and AE pages. Thank you. ' answered with 'The participant self-reported testing positive on 26OCT2020' (Site from DM).	Zoraida Cruz (b) (4)	23 Nov 2020 18:06:48
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	23 Nov 2020 18:04:51
User opened query 'Per CDM: Per CCGs pages 38-39 of CCGs version 2.0 (enter due to SARS-COV-2 if participant is diagnosed). Please confirm if patient was diagnosed. Also complete the Covid-19 Assessment and AE pages. Thank you. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:59:47
User entered 'Protocol directive via ePIP has requested that 2nd dose not be administered. Participant had a positive saliva test that was administered at his worksite.'	Mario Portilla (b) (4)	18 Nov 2020 20:02:07

US3842060

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:57:00

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM: Site response noted. Since participant will continue in the study, please remove all data on this page. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 14:10:26
Query 'Per CDM: Site response noted. Since participant will continue in the study, please remove all data on this page. Thank you.' answered with 'updated.' (Site from DM).	Zoraida Cruz (b) (4)	23 Nov 2020 19:16:28
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Nov 2020 14:57:07
User opened query 'Per CDM: Site response noted. Since participant will continue in the study, please remove all data on this page. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:57:06
Query 'Data is required. Please complete.' answered with 'data entry error, participant consented to continue study without receiving second dose of injection' (Site from System).	Malithi Desilva (b) (4)	18 Nov 2020 20:18:18
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 20:17:33
User entered empty; reason for change New Information	Malithi Desilva (b) (4)	18 Nov 2020 20:17:33
User entered '18 Nov 2020'	Mario Portilla (b) (4)	18 Nov 2020 20:03:46

US3842060

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:57:00

[Reason for discontinuation](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Zoraida Cruz (b) (4)	23 Nov 2020 19:16:13
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Nov 2020 14:57:09
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Mario Portilla (b) (4)	18 Nov 2020 20:39:09
Query 'Data is required. Please complete.' answered with 'data entry error, participant consented to continue study without receiving second dose of injection' (Site from System).	Malithi Desilva (b) (4)	18 Nov 2020 20:18:20
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 20:17:33
User entered empty; reason for change Data Entry Error	Malithi Desilva (b) (4)	18 Nov 2020 20:17:33
User entered 'Study Terminated By Sponsor (STUDY TERMINATED BY SPONSOR)'	Mario Portilla (b) (4)	18 Nov 2020 20:03:46

US3842060

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:57:00

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User entered empty; reason for change Per Query Resolution	Zoraida Cruz (b) (4)	23 Nov 2020 19:16:13
User entered 'protocol deviation' reason for change: Per Query Resolution	Mario Portilla (b) (4)	18 Nov 2020 20:39:09
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	18 Nov 2020 20:17:33
User entered empty; reason for change Per Query Resolution	Malithi Desilva (b) (4)	18 Nov 2020 20:17:33
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	18 Nov 2020 20:06:03
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	18 Nov 2020 20:06:03
User entered 'Positive saliva test. SALIVA WORK AFTER 1ST ADMINISTRATION. EPIP RESPONSE DIRECTED THAT 2ND DOSE NOT BE ADMINISTERED' reason for change: Per Query Resolution	Mario Portilla (b) (4)	18 Nov 2020 20:06:03
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	18 Nov 2020 20:04:52
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	18 Nov 2020 20:04:52

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:57:00

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User entered 'PARTICIPANT HAD A POSITIVE SALIVA TEST AT WORK AFTER 1ST ADMINISTRATION. EPIP response directed that 2nd dose not be administered' reason for change: Per Query Resolution	Mario Portilla (b) (4)	18 Nov 2020 20:04:52
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	18 Nov 2020 20:03:46
User entered 'participant had a positive saliva test at work after 1st administration'	Mario Portilla (b) (4)	18 Nov 2020 20:03:46

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:57:00

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
User entered empty.	Mario Portilla (b) (4)	18 Nov 2020 20:03:46

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:57:00

If main cause of death is Other, specify

Audit	User	Time (GMT)
User entered empty.	Mario Portilla (b) (4)	18 Nov 2020 20:03:46

US3842060

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:57:00

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Mario Portilla (b) (4)	18 Nov 2020 20:03:46

US3842060

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:57:00

[Was autopsy performed?](#)

Audit	User	Time (GMT)
User entered empty.	Mario Portilla (b) (4)	18 Nov 2020 20:03:46