

US3862098 (Prod: Baylor College of Medicine)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:32:46

All time stamps listed in this document are displayed in GMT

US3862098

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 14:20:29

Generated On: 12 Aug 2021 13:32:46

Participant ID

US3862098

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

US3862098

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

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

Visit date (dd MMM yyyy)	31 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3862098

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

Date of Birth (MMM yyyy)	(b) (6) 1975
Age	45
Age Units	YEARS
Age (Derived)	45
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3862098

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 00:39:41

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Date of Informed Consent (<i>dd MMM yyyy</i>)	31 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3862098

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 00:39:41

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Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 00:39:41

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	14:25 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 14:25
Height (xxx.x)	72.5 in
Weight (xxx.x)	222 lb
BMI (xxx.x)	29.75684 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	48 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 00:39:41

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 00:39:41

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

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

Visit date (dd MMM yyyy)	31 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

What was the date of randomization? (dd MMM yyyy) 31 AUG 2020

What was the participant's randomization number? 110388

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	14:25 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 14:25
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	48 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	16:21 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 16:21
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	48 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

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) 31 AUG 2020

What was the treatment time? (00:00-23:59) 15:51 (24 HR)

Treatment Date and Time (derived) 31 AUG 2020 15:51

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	31 AUG 2020
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Collection time (00:00-23:59)	15:08 (24 HR)
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Collection date and time (derived)	31 AUG 2020 15:08
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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

Collection date (dd MMM yyyy)			31 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:50	31 AUG 2020 14:50
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

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: 12 Aug 2021 13:32:46

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 16:22

PC Open Date & Time

31 AUG 2020 16:11

PC Close Date & Time

31 AUG 2020 18:41

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:32:46

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 96.6 °F

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

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

PC Time Stamp	01 SEP 2020 00:06
PC Open Date & Time	31 AUG 2020 19:36
PC Close Date & Time	01 SEP 2020 11:59

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:32:46

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 07:31

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:32:46

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 09:35

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 09:09

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☒

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

Yes ☐

No ☒

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

PC Time Stamp 06 SEP 2020 09:36

PC Open Date & Time 05 SEP 2020 12:00

PC Close Date & Time 06 SEP 2020 11:59

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:32:46

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 ☒

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 07 SEP 2020 09:50

PC Open Date & Time 06 SEP 2020 12:00

PC Close Date & Time 07 SEP 2020 11:59

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:32:46

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

31 AUG 2020 16:24

PC Open Date & Time

31 AUG 2020 16:11

PC Close Date & Time

31 AUG 2020 18:41

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:32:46

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

01 SEP 2020 00:07

PC Open Date & Time

31 AUG 2020 19:36

PC Close Date & Time

01 SEP 2020 11:59

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:32:46

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

02 SEP 2020 07:32

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:32:46

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

04 SEP 2020 09:35

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:32:46

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

05 SEP 2020 09:09

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:32:46

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

06 SEP 2020 09:36

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:32:46

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

07 SEP 2020 09:51

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:32:46

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 16:25
PC Open Date & Time	31 AUG 2020 16:11
PC Close Date & Time	31 AUG 2020 18:41

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:32:46

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 00:08
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PC Open Date & Time	31 AUG 2020 19:36
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PC Close Date & Time	01 SEP 2020 11:59
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US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:32:46

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 ☒

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:32:46

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 07:32
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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Form: General_Day(3)

Generated On: 12 Aug 2021 13:32:46

Yes ☐

PC Time stamp

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:32:46

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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:32:46

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 09:36
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:32:46

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 ☒

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:32:46

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 09:10
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:32:46

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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:32:46

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 09:36
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:32:46

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 ☒

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EAB) (1725)

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:32:46

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 09:51
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3862098

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

DAY 8

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 08 SEP 2020 09:53

PC Open Date & Time 07 SEP 2020 12:00

PC Close Date & Time 08 SEP 2020 11:59

US3862098

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

DAY 9

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

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

09 SEP 2020 10:42

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3862098

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	08 SEP 2020 09:54
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3862098

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	09 SEP 2020 10:52
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3862098

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3862098

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862098

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3862098

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862098

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3862098

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862098

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3862098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 OCT 2020
Time of assessment (00:00-23:59)	13:34 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 13:34
Temperature (xxx.x)	098.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	072 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	167 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	096 mmHg
Diastolic Blood Pressure units	MMHG

US3862098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
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 <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
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	

US3862098

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 OCT 2020

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

US3862098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

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

AE #1: MEDICALLY ATTENDED
NEWLY DIAGNOSED HTN.

PI AND MEDICAL MONITOR
DETERMINED SUBJECT IS NO
LONGER ELIGIBLE FOR DOSE 2
BUT SHOULD CONTINUE IN
STUDY FOR SAFETY AND
EFFICACY ASSESSMENTS.

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? _____

US3862098

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	2 OCT 2020
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Collection time (00:00-23:59)	14:45 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	2 OCT 2020 14:45
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US3862098

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

Collection date (dd MMM yyyy)			2 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	Yes	14:30	2 OCT 2020 14:30

US3862098

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862098

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862098

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862098

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3862098

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862098

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

SUBJECT WAS CALLED THE
23RD AND 26TH OF OCTOBER
MULTIPLE TIMES. HE TOLD US
TO CALL HIM BACK LATER A
COUPLE OF TIMES. HE NEVER
RETURNED OUR PHONE CALLS
OR TEXTS OR ANSWERED
AGAIN.

US3862098

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:39:41

Generated On: 12 Aug 2021 13:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862098

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 15:56:23

Generated On: 12 Aug 2021 13:32:46

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT3

US3862098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Mar 2021 15:56:23

Generated On: 12 Aug 2021 13:32:46

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3862098

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 15:56:23

Generated On: 12 Aug 2021 13:32:46

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.

US3862098

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Mar 2021 15:56:23

Generated On: 12 Aug 2021 13:32:46

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3862098

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:39:42

Generated On: 12 Aug 2021 13:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 NOV 2020 11:30:57
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

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

Date and time of submission

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

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

Date and time of submission

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2020 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2020 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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°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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2020 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2020 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 11:59:45

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 JAN 2021 11:38:49

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 JAN 2021 20:22:51

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 JAN 2021 17:08:52

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 JAN 2021 00:01:49

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 FEB 2021 18:01:07

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 FEB 2021 00:33:15
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 17:59:27

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 FEB 2021 18:59:48
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Date and time of submission

05 MAR 2021 17:58:14

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 MAR 2021 18:06:30
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 MAR 2021 21:35:20
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 MAR 2021 00:28:59

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

31 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 APR 2021 13:13:33
Patient Cloud Open Date & Time	07 APR 2021 00:01
Patient Cloud Close Date & Time	11 APR 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 17:50:22

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 00:25:17

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 12:24:14

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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°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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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°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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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°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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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°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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

25 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2021 00:01
Patient Cloud Close Date & Time	17 OCT 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Patient Cloud Open Date & Time	20 OCT 2021 00:01
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Patient Cloud Close Date & Time	24 OCT 2021 23:59
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US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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°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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

27 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Patient Cloud Open Date & Time	10 NOV 2021 00:01
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Patient Cloud Close Date & Time	14 NOV 2021 23:59
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US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Patient Cloud Open Date & Time	01 DEC 2021 00:01
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Patient Cloud Close Date & Time	05 DEC 2021 23:59
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US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 DEC 2021 00:01
Patient Cloud Close Date & Time	12 DEC 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Patient Cloud Open Date & Time	15 DEC 2021 00:01
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Patient Cloud Close Date & Time	19 DEC 2021 23:59
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US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 DEC 2021 00:01
Patient Cloud Close Date & Time	26 DEC 2021 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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°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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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°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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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°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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 FEB 2022 00:01
Patient Cloud Close Date & Time	27 FEB 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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°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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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°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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JUN 2022 00:01
Patient Cloud Close Date & Time	19 JUN 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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°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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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°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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Patient Cloud Open Date & Time	10 AUG 2022 00:01
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Patient Cloud Close Date & Time	14 AUG 2022 23:59
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US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Patient Cloud Open Date & Time	24 AUG 2022 00:01
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Patient Cloud Close Date & Time	28 AUG 2022 23:59
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US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Patient Cloud Open Date & Time	05 OCT 2022 00:01
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Patient Cloud Close Date & Time	09 OCT 2022 23:59
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US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

12 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

19 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

23 OCT 2022 23:59

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Patient Cloud Open Date & Time	26 OCT 2022 00:01
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Patient Cloud Close Date & Time	30 OCT 2022 23:59
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US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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°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 ☐

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

[Patient Cloud Open Date & Time](#)

02 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2022 23:59

US3862098

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:32:46

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 03:16:48

US3862098

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 22:29:07

Generated On: 12 Aug 2021 13:32:46

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 NOV 2020

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

Comments UNABLE TO REACH SUBJECT,
PD COMPLETED

If Contact Not Made, please provide Comments

US3862098

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 22:29:07

Generated On: 12 Aug 2021 13:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862098

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:20:30

Generated On: 12 Aug 2021 13:32:46

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 31 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3862098

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:20:30

Generated On: 12 Aug 2021 13:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862098

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:20:30

Generated On: 12 Aug 2021 13:32:46

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3862098

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:20:30

Generated On: 12 Aug 2021 13:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862098

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:20:30

Generated On: 12 Aug 2021 13:32:46

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3862098

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:20:30

Generated On: 12 Aug 2021 13:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862098

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:20:30

Generated On: 12 Aug 2021 13:32:46

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

Visit date (dd MMM yyyy)	17 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3862098

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 14:20:30

Generated On: 12 Aug 2021 13:32:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 MAR 2021
Time of assessment (00:00-23:59)	11:39 (24 HR)
Vital Signs Date and Time (derived)	17 MAR 2021 11:39
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3862098

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 14:20:30

Generated On: 12 Aug 2021 13:32:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 MAR 2021

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

US3862098

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 14:20:30

Generated On: 12 Aug 2021 13:32:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 MAR 2021

Collection time (00:00-23:59)

11:46 (24 HR)

Collection date and time (derived)

17 MAR 2021 11:46

US3862098

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:20:30

Generated On: 12 Aug 2021 13:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862098

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:04:01

Generated On: 12 Aug 2021 13:32:46

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3862098

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:04:01

Generated On: 12 Aug 2021 13:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862098

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

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

US3862098

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3862098

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:32:46

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

US3862098

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 12 Aug 2021 13:32:46

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3862098

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:20:29

Generated On: 12 Aug 2021 13:32:46

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

Visit date (dd MMM yyyy)	06 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3862098

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 14:20:29

Generated On: 12 Aug 2021 13:32:46

Date of updated informed consent (dd MMM yyyy)	06 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (dd MMM yyyy)	06 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3862098

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Apr 2021 14:20:29

Generated On: 12 Aug 2021 13:32:46

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3862098

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 14:20:29

Generated On: 12 Aug 2021 13:32:46

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	06 JAN 2021
Time of assessment (00:00-23:59)	09:43 (24 HR)
Vital Signs Date and Time (derived)	06 JAN 2021 09:43
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	45 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3862098

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 14:20:29

Generated On: 12 Aug 2021 13:32:46

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	06 JAN 2021
Time of assessment (00:00-23:59)	12:14 (24 HR)
Vital Signs Date and Time (derived)	06 JAN 2021 12:14
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3862098

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

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 14:20:29

Generated On: 12 Aug 2021 13:32:46

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.

US3862098

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

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 14:20:29

Generated On: 12 Aug 2021 13:32:46

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 06 JAN 2021

What was the treatment time? (00:00-23:59) 11:30 (24 HR)

Treatment Date and Time (derived) 06 JAN 2021 11:30

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

US3862098

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 14:20:29

Generated On: 12 Aug 2021 13:32:46

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	06 JAN 2021
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Collection time (00:00-23:59)	10:21 (24 HR)
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Collection date and time (derived)	06 JAN 2021 10:21
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US3862098

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 14:20:29

Generated On: 12 Aug 2021 13:32:46

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	06 JAN 2021
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Collection time (00:00 - 23:59)	10:15
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Collection Date and Time (derived)	06 JAN 2021 10:15
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US3862098

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

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:20:29

Generated On: 12 Aug 2021 13:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862098

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:20:30

Generated On: 12 Aug 2021 13:32:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862098

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:20:30

Generated On: 12 Aug 2021 13:32:46

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3862098

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:20:29

Generated On: 12 Aug 2021 13:32:46

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

Visit date (dd MMM yyyy)	03 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD29
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US3862098

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 14:20:29

Generated On: 12 Aug 2021 13:32:46

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 FEB 2021
Time of assessment (00:00-23:59)	10:03 (24 HR)
Vital Signs Date and Time (derived)	03 FEB 2021 10:03
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3862098

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 14:20:29

Generated On: 12 Aug 2021 13:32:46

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 FEB 2021
Time of assessment (00:00-23:59)	11:37 (24 HR)
Vital Signs Date and Time (derived)	03 FEB 2021 11:37
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3862098

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 14:20:29

Generated On: 12 Aug 2021 13:32:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 FEB 2021

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

US3862098

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 14:20:29

Generated On: 12 Aug 2021 13:32:46

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 03 FEB 2021

What was the treatment time? (00:00-23:59) 11:07 (24 HR)

Treatment Date and Time (derived) 03 FEB 2021 11:07

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

US3862098

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:20:29

Generated On: 12 Aug 2021 13:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862098

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:20:30

Generated On: 12 Aug 2021 13:32:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862098

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:20:30

Generated On: 12 Aug 2021 13:32:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862098

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:20:29

Generated On: 12 Aug 2021 13:32:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3862098

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 14:20:29

Generated On: 12 Aug 2021 13:32:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 MAR 2021
Time of assessment (00:00-23:59)	11:39 (24 HR)
Vital Signs Date and Time (derived)	17 MAR 2021 11:39
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3862098

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 14:20:29

Generated On: 12 Aug 2021 13:32:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 MAR 2021

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

US3862098

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 14:20:29

Generated On: 12 Aug 2021 13:32:46

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	17 MAR 2021
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Collection time (00:00-23:59)	11:46 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	17 MAR 2021 11:46
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US3862098

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Mar 2021 15:15:20

Generated On: 12 Aug 2021 13:32:46

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3862098

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Mar 2021 15:15:20

Generated On: 12 Aug 2021 13:32:46

AEID	
Adverse event	HYPERTENSION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	29 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	15 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Mar 2021 15:15:20

Generated On: 12 Aug 2021 13:32:46

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input checked="" type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____ _____	
Narrative _____ _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____ _____	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 14:20:29

Generated On: 12 Aug 2021 13:32:46

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

Yes ☒

No ☐

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

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 22:04:01

Generated On: 12 Aug 2021 13:32:46

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication SVT

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 22:04:01

Generated On: 12 Aug 2021 13:32:46

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

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 22:04:01

Generated On: 12 Aug 2021 13:32:46

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☐
No ☒

Indication 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 ☐

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US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 22:04:01

Generated On: 12 Aug 2021 13:32:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 22:04:01

Generated On: 12 Aug 2021 13:32:46

Name of Medication FISH OIL

Prophylaxis Yes ☐
No ☒

Indication 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 ☐

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US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 22:04:01

Generated On: 12 Aug 2021 13:32:46

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

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 22:04:01

Generated On: 12 Aug 2021 13:32:46

Name of Medication MELATONIN

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR INSOMNIA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 22:04:01

Generated On: 12 Aug 2021 13:32:46

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 22:04:01

Generated On: 12 Aug 2021 13:32:46

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 22:04:01

Generated On: 12 Aug 2021 13:32:46

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		19 APR 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 22:04:01

Generated On: 12 Aug 2021 13:32:46

Name of Medication COQ10

Prophylaxis Yes ☒
No ☐

Indication GENERAL WELL-BEING

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 22:04:01

Generated On: 12 Aug 2021 13:32:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 22:04:01

Generated On: 12 Aug 2021 13:32:46

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 22:04:01

Generated On: 12 Aug 2021 13:32:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3862098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 14:20:29

Generated On: 12 Aug 2021 13:32:46

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3862098

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 02 Apr 2021 14:20:29

Generated On: 12 Aug 2021 13:32:46

Date of dosing discontinuation (dd MMM yyyy) 29 SEP 2020

Primary reason for dosing discontinuation

AE (specify)	<input checked="" type="radio"/>
SAE (specify)	<input type="radio"/>
Death	<input type="radio"/>
Lost To Follow-up	<input type="radio"/>
Physician decision (specify)	<input type="radio"/>
Pregnancy	<input type="radio"/>
Protocol deviation (specify)	<input type="radio"/>
Study Terminated By Sponsor	<input type="radio"/>
Withdrawal of consent by participant (specify)	<input type="radio"/>
Due to SARS-COV-2	<input type="radio"/>
Other	<input type="radio"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify AE #1

US3862098

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:32:46

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

US3862098 (Prod: Baylor College of Medicine)

US3862098

Form: Participant Creation

Generated On: 12 Aug 2021 13:32:46

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered 'US3862098'	RWS_ENDPOINT	31 Aug 2020 19:49:45
	ENDPOINT (b) (4)	
	(b) (4)	

US3862098

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:32:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	31 Aug 2020 21:12:20
	(b) (4)	

US3862098

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered '31 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	31 Aug 2020 19:49:46

US3862098

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered 'Clinic (Clinic)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:12:20

US3862098

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:32:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User entered 'SCRN'	System	31 Aug 2020 21:12:20

US3862098

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:32:46

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered (b) (6) 1975'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	31 Aug 2020 19:49:47

US3862098

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:32:46

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '45'	Chanei Henry (b) (4)	31 Aug 2020 21:20:59
	(b) (4)	

US3862098

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:32:46

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User entered 'YEARS'	System	31 Aug 2020 21:20:59

US3862098

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:32:46

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User entered '45'	System	31 Aug 2020 20:56:56

US3862098

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:32:46

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Male (M)'	Chanei Henry (b) (4)	31 Aug 2020 21:20:59
	(b) (4)	

US3862098

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:32:46

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Chanei Henry (b) (4)	31 Aug 2020 21:20:59
	(b) (4)	

US3862098

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:32:46

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '0'	Chanei Henry (b) (4)	31 Aug 2020 21:20:59
	(b) (4)	

US3862098

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:32:46

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'I'	Chanei Henry (b) (4)	31 Aug 2020 21:20:59
	(b) (4)	

US3862098

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:32:46

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '0'	Chanei Henry (b) (4)	31 Aug 2020 21:20:59
	(b) (4)	

US3862098

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:32:46

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '0'	Chanei Henry (b) (4)	31 Aug 2020 21:20:59
	(b) (4)	

US3862098

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:32:46

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '0'	Chanei Henry (b) (4)	31 Aug 2020 21:20:59
	(b) (4)	

US3862098

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:32:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '0'	Chanei Henry (b) (4)	31 Aug 2020 21:20:59
	(b) (4)	

US3862098

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:32:46

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered empty.	Chanei Henry (b) (4)	31 Aug 2020 21:20:59
	(b) (4)	

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Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:32:46

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '0'	Chanei Henry (b) (4)	31 Aug 2020 21:20:59
	(b) (4)	

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Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:32:46

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '0'	Chanei Henry (b) (4)	31 Aug 2020 21:20:59
	(b) (4)	

US3862098

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:32:46

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '31 Aug 2020'	Sandra Francisco (b) (4)	31 Aug 2020 20:56:56
	(b) (4)	

US3862098

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User entered 'Aug 2020'	System	31 Aug 2020 20:56:56

US3862098

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User entered '2020'	System	31 Aug 2020 20:56:56

US3862098

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:32:46

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Amendment 3 (3)'	Sandra Francisco (b) (4)	31 Aug 2020 20:56:56
	(b) (4)	

US3862098

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	31 Aug 2020 20:56:56
	(b) (4)	

US3862098

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:32:46

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	31 Aug 2020 20:56:56
	(b) (4)	

US3862098

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:32:46

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	31 Aug 2020 20:56:56
	(b) (4)	

US3862098

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:32:46

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'No (N)'	Sandra Francisco (b) (4)	31 Aug 2020 20:56:56
	(b) (4)	

US3862098

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:32:46

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	31 Aug 2020 19:49:46

US3862098

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:32:46

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User entered '1'	System	31 Aug 2020 20:56:56

US3862098

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	31 Aug 2020 20:56:33
	(b) (4)	

US3862098

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:32:46

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Yes (Y)'	Chanei Henry (b) (4)	31 Aug 2020 21:21:11
	(b) (4)	

US3862098

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:32:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User closed query 'Per MM, please expand the abbreviation.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 09:27:12
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Supraventricular tachycardia, LLT: Supraventricular tachycardia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 19:21:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 19:21:23
Data point term sent to Coder	System	27 Oct 2020 19:20:40
Query 'Per MM, please expand the abbreviation.' answered with 'Data corrected' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	27 Oct 2020 19:19:47
Coding entries removed.	Shetel Anassi (b) (4) (b) (4)	27 Oct 2020 19:19:41
User entered 'Supraventricular tachycardia' reason for change: Data Entry Error	Shetel Anassi (b) (4) (b) (4)	27 Oct 2020 19:19:41
User opened query 'Per MM, please expand the abbreviation.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 05:49:39
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Supraventricular tachycardia, LLT: Supraventricular tachycardia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 22:21:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 22:21:33
Data point term sent to Coder	System	31 Aug 2020 22:20:46
User entered 'svt'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:20:25

US3862098

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered 'un UNK 2015'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:20:25

US3862098

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:20:25

US3862098

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:32:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	31 Aug 2020 22:20:25
	(b) (4)	

US3862098

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered empty.	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 22:20:25
	(b) (4)	

US3862098

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:32:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:20:25

US3862098

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User entered 'Jan 2015'	System	31 Aug 2020 22:20:25

US3862098

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User entered '2015'	System	31 Aug 2020 22:20:25

US3862098

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User entered empty.	System	31 Aug 2020 22:20:25

US3862098

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User entered empty.	System	31 Aug 2020 22:20:25

US3862098

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:32:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 22:21:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 22:21:33
Data point term sent to Coder	System	31 Aug 2020 22:20:46
User entered 'seasonal allergies'	Carrie Kibler (b) (4)	31 Aug 2020 22:20:43

US3862098

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered 'un UNK 2014'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:20:43

US3862098

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:20:43

US3862098

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:32:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	31 Aug 2020 22:20:43
	(b) (4)	

US3862098

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered empty.	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 22:20:43
	(b) (4)	

US3862098

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:32:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:20:43

US3862098

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User entered 'Jan 2014'	System	31 Aug 2020 22:20:43

US3862098

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User entered '2014'	System	31 Aug 2020 22:20:43

US3862098

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User entered empty.	System	31 Aug 2020 22:20:43

US3862098

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User entered empty.	System	31 Aug 2020 22:20:43

US3862098

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:18:25

US3862098

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered '31 Aug 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:18:25

US3862098

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered '14:25'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:18:25

US3862098

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User entered '31 Aug 2020 14:25'	System	31 Aug 2020 22:18:25

US3862098

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered '72.5' in	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 22:18:25
DataPoint set to visible.	(b) (4) System	31 Aug 2020 20:56:56

US3862098

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered '222' lb	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 22:18:25
DataPoint set to visible.	(b) (4) System	31 Aug 2020 20:56:56

US3862098

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User entered '29.75684'	System	31 Aug 2020 22:18:25
DataPoint set to visible.	System	31 Aug 2020 20:56:56

US3862098

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User entered 'kg/m2'	System	31 Aug 2020 22:18:25
DataPoint set to visible.	System	31 Aug 2020 20:56:56

US3862098

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '98.4' F	Carrie Kibler (b) (4)	31 Aug 2020 22:18:25
	(b) (4)	

US3862098

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Oral (Oral)'	Carrie Kibler (b) (4)	31 Aug 2020 22:18:25
	(b) (4)	

US3862098

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered empty.	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 22:18:25
	(b) (4)	

US3862098

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered '48'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:18:25

US3862098

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User entered 'bpm'	System	31 Aug 2020 22:18:25

US3862098

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered '14'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:18:25

US3862098

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User entered 'breaths/min'	System	31 Aug 2020 22:18:25

US3862098

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered '130'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:18:25

US3862098

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User entered 'mmHg'	System	31 Aug 2020 22:18:25

US3862098

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered '88'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:18:25

US3862098

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User entered 'mmHg'	System	31 Aug 2020 22:18:25

US3862098

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42

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Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42

US3862098

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:32:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:12:01

US3862098

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:32:46

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered '31 Aug 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:12:01

US3862098

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:19:08

US3862098

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	31 Aug 2020 22:19:08
	(b) (4)	

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:19:08

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Folder: Screening

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 22:19:08
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:19:08

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 22:19:08
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 22:19:08
	(b) (4)	

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Folder: Screening

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 22:19:08
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	31 Aug 2020 22:19:08
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:19:08

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:19:08

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	31 Aug 2020 22:19:08
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:46

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:19:08

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:46

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User closed query "No Risk Identified' is not checked, however no other risks are selected. Please review and reconcile.' (Site from System).	System	31 Aug 2020 22:19:18
User opened query "No Risk Identified' is not checked, however no other risks are selected. Please review and reconcile.' (Site from System).	System	31 Aug 2020 22:19:08
User entered '0'	Carrie Kibler (b) (4)	31 Aug 2020 22:19:08
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:19:08

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:19:08

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered '1' reason for change: Data Entry Error	(b) (4)	31 Aug 2020 22:19:18
User entered '0'	Carrie Kibler (b) (4)	31 Aug 2020 22:19:08
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:19:08

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:19:08

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:19:08

US3862098

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:46

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:19:08

US3862098

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:32:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	31 Aug 2020 21:12:29
	(b) (4)	

US3862098

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '31 Aug 2020'	Carrie Kibler (b) (4)	31 Aug 2020 21:12:29
	(b) (4)	

US3862098

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered 'Clinic (Clinic)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:12:29

US3862098

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:32:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User entered 'VISIT1'	System	31 Aug 2020 21:12:29

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered '31 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	31 Aug 2020 20:29:25

US3862098

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered '110388'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	31 Aug 2020 20:29:25

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	31 Aug 2020 20:29:25

US3862098

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'No (N)'	Chanei Henry (b) (4)	31 Aug 2020 21:17:47
	(b) (4)	

US3862098

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered 'No (N)'	(b) (4) Chanei Henry (b) (4)	31 Aug 2020 21:17:47
	(b) (4)	

US3862098

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'No (N)'	Chanei Henry (b) (4)	31 Aug 2020 21:17:47
	(b) (4)	

US3862098

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:32:46

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'No (N)'	Chanei Henry (b) (4)	31 Aug 2020 21:17:47
	(b) (4)	

US3862098

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:32:46

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'No (N)'	Chanei Henry (b) (4)	31 Aug 2020 21:17:47
	(b) (4)	

US3862098

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4)	22 Sep 2020 18:25:24
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 08:49:22
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:49:21

US3862098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:32:46

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:06:04
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' answered with 'Data corrected' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 16:39:00
User entered missing code ND - Not Done; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 16:38:37
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 06:29:56
User entered '72.5' in	Chanei Henry (b) (4) (b) (4)	31 Aug 2020 21:19:35

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:32:46

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Shetel Anassi (b) (4)	20 Oct 2020 16:38:42
	(b) (4)	
User entered '222.0' lb	Chanei Henry (b) (4)	31 Aug 2020 21:19:35
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:32:46

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:06:04
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' answered with 'Data corrected' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 16:39:00
User entered missing code ND - Not Done; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 16:38:37
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 06:29:56
User entered '72.5' in	Chanei Henry (b) (4) (b) (4)	31 Aug 2020 21:19:35

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:32:46

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Shetel Anassi (b) (4)	20 Oct 2020 16:38:42
	(b) (4)	
User entered '222.0' lb	Chanei Henry (b) (4)	31 Aug 2020 21:19:35
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User accepted default value 'Pre-Dose (PREDOSE)'	Chanei Henry (b) (4) (b) (4)	31 Aug 2020 21:19:35

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Yes (Y)'	Chanei Henry (b) (4)	31 Aug 2020 21:19:35
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '31 Aug 2020'	Chanei Henry (b) (4)	31 Aug 2020 21:19:35
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '14:25'	Chanei Henry (b) (4)	31 Aug 2020 21:19:35
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User entered '31 Aug 2020 14:25'	System	31 Aug 2020 21:19:35

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '98.4' F	Chanei Henry (b) (4)	31 Aug 2020 21:19:35
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Oral (Oral)'	Chanei Henry (b) (4)	31 Aug 2020 21:19:35
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered empty.	Chanei Henry (b) (4)	31 Aug 2020 21:19:35
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '48'	Chanei Henry (b) (4)	31 Aug 2020 21:19:35
	(b) (4)	

US3862098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User entered 'bpm'	System	31 Aug 2020 21:19:35

US3862098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '14'	Chanei Henry (b) (4)	31 Aug 2020 21:19:35
	(b) (4)	

US3862098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User entered 'breaths/min'	System	31 Aug 2020 21:19:35

US3862098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '130'	Chanei Henry (b) (4)	31 Aug 2020 21:19:35
	(b) (4)	

US3862098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User entered 'mmHg'	System	31 Aug 2020 21:19:35

US3862098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '88'	Chanei Henry (b) (4)	31 Aug 2020 21:19:35
	(b) (4)	

US3862098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User entered 'mmHg'	System	31 Aug 2020 21:19:35

US3862098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:32:46

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:06:04
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' answered with 'Data corrected' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 16:39:00
User entered missing code ND - Not Done; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 16:38:37
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 06:29:56
User entered '72.5' in	Chanei Henry (b) (4) (b) (4)	31 Aug 2020 21:19:35

US3862098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:32:46

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Shetel Anassi (b) (4)	20 Oct 2020 16:38:42
	(b) (4)	
User entered '222.0' lb	Chanei Henry (b) (4)	31 Aug 2020 21:19:35
	(b) (4)	

US3862098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User accepted default value 'Post-Dose (POSTDOSE)'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:19:59

US3862098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:19:59

US3862098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '31 Aug 2020'	Carrie Kibler (b) (4)	31 Aug 2020 22:19:59
	(b) (4)	

US3862098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered '16:21'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:19:59

US3862098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User entered '31 Aug 2020 16:21'	System	31 Aug 2020 22:19:59

US3862098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '98.5' F	Carrie Kibler (b) (4)	31 Aug 2020 22:19:59
	(b) (4)	

US3862098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Oral (Oral)'	Carrie Kibler (b) (4)	31 Aug 2020 22:19:59
	(b) (4)	

US3862098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:19:59

US3862098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered '48'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:19:59

US3862098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User entered 'bpm'	System	31 Aug 2020 22:19:59

US3862098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered '12'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:19:59

US3862098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User entered 'breaths/min'	System	31 Aug 2020 22:19:59

US3862098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered '146'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:19:59

US3862098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User entered 'mmHg'	System	31 Aug 2020 22:19:59

US3862098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered '81'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:19:59

US3862098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User entered 'mmHg'	System	31 Aug 2020 22:19:59

US3862098

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:32:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	31 Aug 2020 21:12:08
	(b) (4)	

US3862098

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:32:46

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '31 Aug 2020'	Carrie Kibler (b) (4)	31 Aug 2020 21:12:08
	(b) (4)	

US3862098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	31 Aug 2020 20:57:43
	(b) (4)	

US3862098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	31 Aug 2020 20:57:43
	(b) (4)	

US3862098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered empty.	(b) (4) Sandra Francisco (b) (4)	31 Aug 2020 20:57:43
	(b) (4)	

US3862098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User entered 'MRNA-1273 OR PLACEBO'	System	31 Aug 2020 20:57:43

US3862098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '31 Aug 2020'	Sandra Francisco (b) (4)	31 Aug 2020 20:57:43
	(b) (4)	

US3862098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '15:51'	Sandra Francisco (b) (4)	31 Aug 2020 20:57:43
	(b) (4)	

US3862098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User entered '31 Aug 2020 15:51'	System	31 Aug 2020 20:57:43

US3862098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Sandra Francisco (b) (4)	31 Aug 2020 20:57:43
	(b) (4)	

US3862098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User entered 'ONCE'	System	31 Aug 2020 20:57:43

US3862098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User entered 'INTRAMUSCULAR'	System	31 Aug 2020 20:57:43

US3862098

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Yes (Y)'	Chanei Henry (b) (4)	31 Aug 2020 21:15:24
	(b) (4)	

US3862098

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '31 Aug 2020'	Chanei Henry (b) (4)	31 Aug 2020 21:15:24
	(b) (4)	

US3862098

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '15:08'	Chanei Henry (b) (4)	31 Aug 2020 21:15:24
	(b) (4)	

US3862098

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User entered '31 Aug 2020 15:08'	System	31 Aug 2020 21:15:24

US3862098

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:32:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '31 Aug 2020'	Chanei Henry (b) (4)	31 Aug 2020 21:15:41
	(b) (4)	

US3862098

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:32:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Chanei Henry (b) (4) (b) (4)	31 Aug 2020 21:15:41

US3862098

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:32:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Yes (Y)'	Chanei Henry (b) (4)	31 Aug 2020 21:15:41
	(b) (4)	

US3862098

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:32:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '14:50'	Chanei Henry (b) (4)	31 Aug 2020 21:15:41
	(b) (4)	

US3862098

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User entered '31 Aug 2020 14:50'	System	31 Aug 2020 21:15:41

US3862098

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:32:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Chanei Henry (b) (4) (b) (4)	31 Aug 2020 21:15:41

US3862098

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:32:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'No (N)'	Chanei Henry (b) (4)	31 Aug 2020 21:15:41
	(b) (4)	

US3862098

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:32:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered empty.	Chanei Henry (b) (4)	31 Aug 2020 21:15:41
	(b) (4)	

US3862098

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User entered empty.	System	31 Aug 2020 21:15:41

US3862098

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:12:12

US3862098

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User entered '1'	System	31 Aug 2020 21:12:12

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
Data entry locked.	System	31 Aug 2020 20:57:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:32:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-08-31T16:22:16', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '6e99640c-b05d-4906-ae20-c02fda1b500d' User entered 'Yes (Y)'	System	31 Aug 2020 21:22:55
	System	31 Aug 2020 21:22:55

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:32:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-08-31T16:22:25', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '6e99640c-b05d-4906-ae20-c02fda1b500d' User entered '98.5'	System	31 Aug 2020 21:22:55
	System	31 Aug 2020 21:22:55

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-08-31T16:22:30', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '6e99640c-b05d-4906-ae20-c02fda1b500d'	System	31 Aug 2020 21:22:55
User entered 'No (N)'	System	31 Aug 2020 21:22:55

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-08-31T16:22:52', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '6e99640c-b05d-4906-ae20-c02fda1b500d' User entered '31 Aug 2020 16:22'	System	31 Aug 2020 21:22:55
	System	31 Aug 2020 21:22:55

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '31 Aug 2020 16:11'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '31 Aug 2020 18:41'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
Data entry locked.	System	31 Aug 2020 20:57:43
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:32:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-01T00:06:05', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '035625bb-44f1-4c64-afca-b377a4ddb9c9' User entered 'Yes (Y)'	System	01 Sep 2020 05:06:33
	System	01 Sep 2020 05:06:33

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:32:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-01T00:06:16', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '035625bb-44f1-4c64-afca-b377a4ddb9c9' User entered '96.6'	System	01 Sep 2020 05:06:33
	System	01 Sep 2020 05:06:33

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-01T00:06:23', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '035625bb-44f1-4c64-afca-b377a4ddb9c9'	System	01 Sep 2020 05:06:33
User entered 'No (N)'	System	01 Sep 2020 05:06:33

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-01T00:06:32', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '035625bb-44f1-4c64-afca-b377a4ddb9c9'	System	01 Sep 2020 05:06:33
User entered '01 Sep 2020 00:06'	System	01 Sep 2020 05:06:33

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '31 Aug 2020 19:36'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
Data entry locked.	System	31 Aug 2020 20:57:43
User entered 'Day 2'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:32:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-02T07:29:54', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '80b6cd8f-b2b2-41ee-932a-53496f3cd7e1' User entered 'Yes (Y)'	System	02 Sep 2020 12:31:54
	System	02 Sep 2020 12:31:54

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:32:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-02T07:31:42', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '80b6cd8f-b2b2-41ee-932a-53496f3cd7e1' User entered '97.5'	System	02 Sep 2020 12:31:54
	System	02 Sep 2020 12:31:54

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-02T07:31:46', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '80b6cd8f-b2b2-41ee-932a-53496f3cd7e1'	System	02 Sep 2020 12:31:54
User entered 'No (N)'	System	02 Sep 2020 12:31:54

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-02T07:31:52', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '80b6cd8f-b2b2-41ee-932a-53496f3cd7e1' User entered '02 Sep 2020 07:31'	System	02 Sep 2020 12:31:54
	System	02 Sep 2020 12:31:54

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
Data entry locked.	System	31 Aug 2020 20:57:43
User entered 'Day 3'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:32:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:32:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:32:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
Data entry locked.	System	31 Aug 2020 20:57:43
User entered 'Day 4'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:32:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-04T09:35:19', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '2ebbb156-3813-4bee-979f-e10bb5b5fdd2'	System	04 Sep 2020 14:35:37
User entered 'Yes (Y)'	System	04 Sep 2020 14:35:37

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:32:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-04T09:35:25', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '2ebbb156-3813-4bee-979f-e10bb5b5fdd2' User entered '98.1'	System	04 Sep 2020 14:35:37
	System	04 Sep 2020 14:35:37

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-04T09:35:30', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '2ebbb156-3813-4bee-979f-e10bb5b5fdd2'	System	04 Sep 2020 14:35:37
User entered 'No (N)'	System	04 Sep 2020 14:35:37

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-04T09:35:34', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '2ebbb156-3813-4bee-979f-e10bb5b5fdd2'	System	04 Sep 2020 14:35:37
User entered '04 Sep 2020 09:35'	System	04 Sep 2020 14:35:37

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
Data entry locked.	System	31 Aug 2020 20:57:43
User entered 'Day 5'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:32:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-05T09:09:21', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '70502502-74cc-47ff-80b9-3f92each8f0c' User entered 'Yes (Y)'	System	05 Sep 2020 14:09:39
	System	05 Sep 2020 14:09:39

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:32:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-05T09:09:28', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '70502502-74cc-47ff-80b9-3f92each8f0c' User entered '97.1'	System	05 Sep 2020 14:09:39
	System	05 Sep 2020 14:09:39

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-05T09:09:31', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '70502502-74cc-47ff-80b9-3f92each8f0c'	System	05 Sep 2020 14:09:39
User entered 'No (N)'	System	05 Sep 2020 14:09:39

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-05T09:09:36', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '70502502-74cc-47ff-80b9-3f92each8f0c'	System	05 Sep 2020 14:09:39
User entered '05 Sep 2020 09:09'	System	05 Sep 2020 14:09:39

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
Data entry locked.	System	31 Aug 2020 20:57:43
User entered 'Day 6'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:32:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-06T09:35:53', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'aa111c50-4d9f-45bf-8795-b421047b5c1c' User entered 'No (N)'	System	06 Sep 2020 14:36:03
	System	06 Sep 2020 14:36:03

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-06T09:35:56', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'aa111c50-4d9f-45bf-8795-b421047b5c1c' User entered 'No (N)'	System	06 Sep 2020 14:36:03
	System	06 Sep 2020 14:36:03

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-06T09:36:02', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'aa111c50-4d9f-45bf-8795-b421047b5c1c' User entered '06 Sep 2020 09:36'	System	06 Sep 2020 14:36:03
	System	06 Sep 2020 14:36:03

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
Data entry locked.	System	31 Aug 2020 20:57:43
User entered 'Day 7'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:32:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-07T09:50:50', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'd33c3adb-76a3-49a5-b355-d43d9098f4d2' User entered 'No (N)'	System	07 Sep 2020 14:51:01
	System	07 Sep 2020 14:51:01

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-07T09:50:53', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'd33c3adb-76a3-49a5-b355-d43d9098f4d2'	System	07 Sep 2020 14:51:01
User entered 'No (N)'	System	07 Sep 2020 14:51:01

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-07T09:50:57', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'd33c3adb-76a3-49a5-b355-d43d9098f4d2'	System	07 Sep 2020 14:51:01
User entered '07 Sep 2020 09:50'	System	07 Sep 2020 14:51:01

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
Data entry locked.	System	31 Aug 2020 20:57:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:32:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-08-31T16:23:12', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '7c8e79d5-1db8-4623-8951-3765e6147e13'	System	31 Aug 2020 21:24:22
User entered 'None (1)'	System	31 Aug 2020 21:24:22

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:32:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-08-31T16:23:41', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '7c8e79d5-1db8-4623-8951-3765e6147e13'	System	31 Aug 2020 21:24:22
User entered 'No (N)'	System	31 Aug 2020 21:24:22

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-08-31T16:23:44', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '7c8e79d5-1db8-4623-8951-3765e6147e13'	System	31 Aug 2020 21:24:22
User entered 'No (N)'	System	31 Aug 2020 21:24:22

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:32:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-08-31T16:24:10', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '7c8e79d5-1db8-4623-8951-3765e6147e13'	System	31 Aug 2020 21:24:22
User entered 'None (1)'	System	31 Aug 2020 21:24:22

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-08-31T16:24:20', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '7c8e79d5-1db8-4623-8951-3765e6147e13'	System	31 Aug 2020 21:24:22
User entered '31 Aug 2020 16:24'	System	31 Aug 2020 21:24:22

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '31 Aug 2020 16:11'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '31 Aug 2020 18:41'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
Data entry locked.	System	31 Aug 2020 20:57:43
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:32:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-01T00:06:51', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '634e2ed1-2d20-4e61-bb52-efff20be5d3a' User entered 'None (1)'	System	01 Sep 2020 05:07:18
	System	01 Sep 2020 05:07:18

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:32:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-01T00:06:57', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '634e2ed1-2d20-4e61-bb52-efff20be5d3a' User entered 'No (N)'	System	01 Sep 2020 05:07:18
	System	01 Sep 2020 05:07:18

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-01T00:07:04', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '634e2ed1-2d20-4e61-bb52-efff20be5d3a' User entered 'No (N)'	System	01 Sep 2020 05:07:18
	System	01 Sep 2020 05:07:18

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:32:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-01T00:07:13', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '634e2ed1-2d20-4e61-bb52-efff20be5d3a' User entered 'None (1)'	System	01 Sep 2020 05:07:18
	System	01 Sep 2020 05:07:18

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-01T00:07:17', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '634e2ed1-2d20-4e61-bb52-efff20be5d3a' User entered '01 Sep 2020 00:07'	System	01 Sep 2020 05:07:18
	System	01 Sep 2020 05:07:18

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '31 Aug 2020 19:36'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
Data entry locked.	System	31 Aug 2020 20:57:43
User entered 'Day 2'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:32:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-02T07:31:58', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '07ab9ef7-48b2-43af-8b4a-5d439654801c' User entered 'None (1)'	System	02 Sep 2020 12:32:14
	System	02 Sep 2020 12:32:14

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:32:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-02T07:32:01', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '07ab9ef7-48b2-43af-8b4a-5d439654801c' User entered 'No (N)'	System	02 Sep 2020 12:32:14
	System	02 Sep 2020 12:32:14

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-02T07:32:04', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '07ab9ef7-48b2-43af-8b4a-5d439654801c' User entered 'No (N)'	System	02 Sep 2020 12:32:14
	System	02 Sep 2020 12:32:14

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:32:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-02T07:32:08', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '07ab9ef7-48b2-43af-8b4a-5d439654801c' User entered 'None (1)'	System	02 Sep 2020 12:32:14
	System	02 Sep 2020 12:32:14

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-02T07:32:11', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '07ab9ef7-48b2-43af-8b4a-5d439654801c' User entered '02 Sep 2020 07:32'	System	02 Sep 2020 12:32:14
	System	02 Sep 2020 12:32:14

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
Data entry locked.	System	31 Aug 2020 20:57:43
User entered 'Day 3'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:32:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:32:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:32:46

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:32:46

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:32:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
Data entry locked.	System	31 Aug 2020 20:57:43
User entered 'Day 4'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:32:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-04T09:35:38', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'ecea2407-e636-4e02-9fbb-017e8119e217'	System	04 Sep 2020 14:35:54
User entered 'None (1)'	System	04 Sep 2020 14:35:54

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:32:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-04T09:35:40', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'ecea2407-e636-4e02-9fbb-017e8119e217'	System	04 Sep 2020 14:35:54
User entered 'No (N)'	System	04 Sep 2020 14:35:54

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-04T09:35:46', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'ecea2407-e636-4e02-9fbb-017e8119e217'	System	04 Sep 2020 14:35:54
User entered 'No (N)'	System	04 Sep 2020 14:35:54

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:32:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-04T09:35:50', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'ecea2407-e636-4e02-9fbb-017e8119e217'	System	04 Sep 2020 14:35:54
User entered 'None (1)'	System	04 Sep 2020 14:35:54

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-04T09:35:52', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'ecea2407-e636-4e02-9fbb-017e8119e217'	System	04 Sep 2020 14:35:54
User entered '04 Sep 2020 09:35'	System	04 Sep 2020 14:35:54

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
Data entry locked.	System	31 Aug 2020 20:57:43
User entered 'Day 5'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:32:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-05T09:09:40', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'f767c9da-ed35-4036-b917-c0b17de07ccd'	System	05 Sep 2020 14:10:03
User entered 'None (1)'	System	05 Sep 2020 14:10:03

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:32:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-05T09:09:45', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'f767c9da-ed35-4036-b917-c0b17de07ccd' User entered 'No (N)'	System	05 Sep 2020 14:10:03
	System	05 Sep 2020 14:10:03

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-05T09:09:49', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'f767c9da-ed35-4036-b917-c0b17de07ccd' User entered 'No (N)'	System	05 Sep 2020 14:10:03
	System	05 Sep 2020 14:10:03

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:32:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-05T09:09:53', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'f767c9da-ed35-4036-b917-c0b17de07ccd' User entered 'None (1)'	System	05 Sep 2020 14:10:03
	System	05 Sep 2020 14:10:03

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-05T09:09:59', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'f767c9da-ed35-4036-b917-c0b17de07ccd' User entered '05 Sep 2020 09:09'	System	05 Sep 2020 14:10:03
	System	05 Sep 2020 14:10:03

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
Data entry locked.	System	31 Aug 2020 20:57:43
User entered 'Day 6'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:32:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-06T09:36:06', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'f00c85cc-60d9-4336-a132-811f3135ae1b' User entered 'None (1)'	System	06 Sep 2020 14:36:18
	System	06 Sep 2020 14:36:18

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:32:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-06T09:36:09', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'f00c85cc-60d9-4336-a132-811f3135ae1b' User entered 'No (N)'	System	06 Sep 2020 14:36:18
	System	06 Sep 2020 14:36:18

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-06T09:36:12', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'f00c85cc-60d9-4336-a132-811f3135ae1b' User entered 'No (N)'	System	06 Sep 2020 14:36:18
	System	06 Sep 2020 14:36:18

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:32:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-06T09:36:15', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'f00c85cc-60d9-4336-a132-811f3135ae1b' User entered 'None (1)'	System	06 Sep 2020 14:36:18
	System	06 Sep 2020 14:36:18

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-06T09:36:17', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'f00c85cc-60d9-4336-a132-811f3135ae1b' User entered '06 Sep 2020 09:36'	System	06 Sep 2020 14:36:18
	System	06 Sep 2020 14:36:18

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
Data entry locked.	System	31 Aug 2020 20:57:43
User entered 'Day 7'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:32:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-07T09:51:01', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '34325dc7-157a-4548-86ef-47c117beff2f' User entered 'None (1)'	System	07 Sep 2020 14:51:14
	System	07 Sep 2020 14:51:14

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:32:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-07T09:51:03', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '34325dc7-157a-4548-86ef-47c117beff2f' User entered 'No (N)'	System	07 Sep 2020 14:51:14
	System	07 Sep 2020 14:51:14

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-07T09:51:06', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '34325dc7-157a-4548-86ef-47c117beff2f' User entered 'No (N)'	System	07 Sep 2020 14:51:14
	System	07 Sep 2020 14:51:14

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:32:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-07T09:51:09', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '34325dc7-157a-4548-86ef-47c117beff2f' User entered 'None (1)'	System	07 Sep 2020 14:51:14
	System	07 Sep 2020 14:51:14

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:32:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-07T09:51:12', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '34325dc7-157a-4548-86ef-47c117beff2f' User entered '07 Sep 2020 09:51'	System	07 Sep 2020 14:51:14
	System	07 Sep 2020 14:51:14

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
Data entry locked.	System	31 Aug 2020 20:57:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:32:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-08-31T16:24:34', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '94b4e278-91be-4611-aca0-7cb2acaf10bf' User entered 'None (0)'	System	31 Aug 2020 21:25:43
	System	31 Aug 2020 21:25:43

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:32:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-08-31T16:24:38', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '94b4e278-91be-4611-aca0-7cb2acaf10bf' User entered 'None (0)'	System	31 Aug 2020 21:25:43
	System	31 Aug 2020 21:25:43

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:32:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-08-31T16:24:53', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '94b4e278-91be-4611-aca0-7cb2acaf10bf' User entered 'None (0)'	System	31 Aug 2020 21:25:43
	System	31 Aug 2020 21:25:43

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:32:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-08-31T16:24:58', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '94b4e278-91be-4611-aca0-7cb2acaf10bf' User entered 'None (0)'	System	31 Aug 2020 21:25:43
	System	31 Aug 2020 21:25:43

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:32:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-08-31T16:25:01', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '94b4e278-91be-4611-aca0-7cb2acaf10bf' User entered 'None (0)'	System	31 Aug 2020 21:25:43
	System	31 Aug 2020 21:25:43

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:32:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-08-31T16:25:04', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '94b4e278-91be-4611-aca0-7cb2acaf10bf' User entered 'None (0)'	System	31 Aug 2020 21:25:43
	System	31 Aug 2020 21:25:43

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-08-31T16:25:38', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '94b4e278-91be-4611-aca0-7cb2acaf10bf'	System	31 Aug 2020 21:25:43
User entered 'No (N)'	System	31 Aug 2020 21:25:43

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-08-31T16:25:40', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '94b4e278-91be-4611-aca0-7cb2acaf10bf' User entered '31 Aug 2020 16:25'	System	31 Aug 2020 21:25:43
	System	31 Aug 2020 21:25:43

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '31 Aug 2020 16:11'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '31 Aug 2020 18:41'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
Data entry locked.	System	31 Aug 2020 20:57:43
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:32:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-01T00:07:26', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '9358820c-6e74-4562-9292-b8b61cafaf7b' User entered 'None (0)'	System	01 Sep 2020 05:08:08
	System	01 Sep 2020 05:08:08

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:32:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-01T00:07:33', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '9358820c-6e74-4562-9292-b8b61cafaf7b' User entered 'None (0)'	System	01 Sep 2020 05:08:08
	System	01 Sep 2020 05:08:08

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:32:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-01T00:07:36', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '9358820c-6e74-4562-9292-b8b61cafaf7b' User entered 'None (0)'	System	01 Sep 2020 05:08:08
	System	01 Sep 2020 05:08:08

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:32:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-01T00:07:40', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '9358820c-6e74-4562-9292-b8b61cafaf7b' User entered 'None (0)'	System	01 Sep 2020 05:08:08
	System	01 Sep 2020 05:08:08

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:32:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-01T00:07:45', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '9358820c-6e74-4562-9292-b8b61cafaf7b' User entered 'None (0)'	System	01 Sep 2020 05:08:08
	System	01 Sep 2020 05:08:08

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:32:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-01T00:07:49', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '9358820c-6e74-4562-9292-b8b61cafaf7b' User entered 'None (0)'	System	01 Sep 2020 05:08:08
	System	01 Sep 2020 05:08:08

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-01T00:08:00', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '9358820c-6e74-4562-9292-b8b61cafaf7b' User entered 'No (N)'	System	01 Sep 2020 05:08:08
	System	01 Sep 2020 05:08:08

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-01T00:08:05', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '9358820c-6e74-4562-9292-b8b61cafaf7b' User entered '01 Sep 2020 00:08'	System	01 Sep 2020 05:08:08
	System	01 Sep 2020 05:08:08

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '31 Aug 2020 19:36'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
Data entry locked.	System	31 Aug 2020 20:57:43
User entered 'Day 2'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:32:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-02T07:32:16', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '81c30908-78f3-44b9-a6e9-fc0a2496909e' User entered 'None (0)'	System	02 Sep 2020 12:32:39
	System	02 Sep 2020 12:32:39

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:32:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-02T07:32:19', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '81c30908-78f3-44b9-a6e9-fc0a2496909e' User entered 'None (0)'	System	02 Sep 2020 12:32:39
	System	02 Sep 2020 12:32:39

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:32:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-02T07:32:21', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '81c30908-78f3-44b9-a6e9-fc0a2496909e' User entered 'None (0)'	System	02 Sep 2020 12:32:39
	System	02 Sep 2020 12:32:39

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:32:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-02T07:32:23', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '81c30908-78f3-44b9-a6e9-fc0a2496909e' User entered 'None (0)'	System	02 Sep 2020 12:32:39
	System	02 Sep 2020 12:32:39

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:32:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-02T07:32:26', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '81c30908-78f3-44b9-a6e9-fc0a2496909e' User entered 'None (0)'	System	02 Sep 2020 12:32:39
	System	02 Sep 2020 12:32:39

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:32:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-02T07:32:28', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '81c30908-78f3-44b9-a6e9-fc0a2496909e' User entered 'None (0)'	System	02 Sep 2020 12:32:39
	System	02 Sep 2020 12:32:39

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-02T07:32:34', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '81c30908-78f3-44b9-a6e9-fc0a2496909e'	System	02 Sep 2020 12:32:39
User entered 'No (N)'	System	02 Sep 2020 12:32:39

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-02T07:32:37', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '81c30908-78f3-44b9-a6e9-fc0a2496909e' User entered '02 Sep 2020 07:32'	System	02 Sep 2020 12:32:39
	System	02 Sep 2020 12:32:39

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
Data entry locked.	System	31 Aug 2020 20:57:43
User entered 'Day 3'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:32:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:32:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:32:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:32:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:32:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:32:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
Data entry locked.	System	31 Aug 2020 20:57:43
User entered 'Day 4'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:32:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-04T09:35:56', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'c54a85ca-9e32-46a0-bc0f-8cfbe236d308'	System	04 Sep 2020 14:36:19
User entered 'None (0)'	System	04 Sep 2020 14:36:19

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:32:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-04T09:35:59', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'c54a85ca-9e32-46a0-bc0f-8cfbe236d308'	System	04 Sep 2020 14:36:19
User entered 'None (0)'	System	04 Sep 2020 14:36:19

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:32:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-04T09:36:03', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'c54a85ca-9e32-46a0-bc0f-8cfbe236d308'	System	04 Sep 2020 14:36:19
User entered 'None (0)'	System	04 Sep 2020 14:36:19

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:32:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-04T09:36:05', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'c54a85ca-9e32-46a0-bc0f-8cfbe236d308'	System	04 Sep 2020 14:36:19
User entered 'None (0)'	System	04 Sep 2020 14:36:19

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:32:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-04T09:36:09', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'c54a85ca-9e32-46a0-bc0f-8cfbe236d308'	System	04 Sep 2020 14:36:19
User entered 'None (0)'	System	04 Sep 2020 14:36:19

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:32:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-04T09:36:10', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'c54a85ca-9e32-46a0-bc0f-8cfbe236d308'	System	04 Sep 2020 14:36:19
User entered 'None (0)'	System	04 Sep 2020 14:36:19

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-04T09:36:14', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'c54a85ca-9e32-46a0-bc0f-8cfbe236d308'	System	04 Sep 2020 14:36:19
User entered 'No (N)'	System	04 Sep 2020 14:36:19

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-04T09:36:18', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'c54a85ca-9e32-46a0-bc0f-8cfbe236d308'	System	04 Sep 2020 14:36:19
User entered '04 Sep 2020 09:36'	System	04 Sep 2020 14:36:19

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
Data entry locked.	System	31 Aug 2020 20:57:43
User entered 'Day 5'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:32:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-05T09:10:03', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '0677714e-b088-40c2-9acb-1ef9f5774f39' User entered 'None (0)'	System	05 Sep 2020 14:10:49
	System	05 Sep 2020 14:10:49

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:32:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-05T09:10:08', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '0677714e-b088-40c2-9acb-1ef9f5774f39'	System	05 Sep 2020 14:10:49
User entered 'None (0)'	System	05 Sep 2020 14:10:49

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:32:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-05T09:10:20', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '0677714e-b088-40c2-9acb-1ef9f5774f39'	System	05 Sep 2020 14:10:49
User entered 'No interference with activity (1)'	System	05 Sep 2020 14:10:49

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:32:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-05T09:10:31', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '0677714e-b088-40c2-9acb-1ef9f5774f39' User entered 'None (0)'	System	05 Sep 2020 14:10:49
	System	05 Sep 2020 14:10:49

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:32:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-05T09:10:34', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '0677714e-b088-40c2-9acb-1ef9f5774f39' User entered 'None (0)'	System	05 Sep 2020 14:10:49
	System	05 Sep 2020 14:10:49

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:32:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-05T09:10:39', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '0677714e-b088-40c2-9acb-1ef9f5774f39' User entered 'None (0)'	System	05 Sep 2020 14:10:49
	System	05 Sep 2020 14:10:49

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-05T09:10:45', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '0677714e-b088-40c2-9acb-1ef9f5774f39'	System	05 Sep 2020 14:10:49
User entered 'No (N)'	System	05 Sep 2020 14:10:49

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-05T09:10:47', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '0677714e-b088-40c2-9acb-1ef9f5774f39'	System	05 Sep 2020 14:10:49
User entered '05 Sep 2020 09:10'	System	05 Sep 2020 14:10:49

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
Data entry locked.	System	31 Aug 2020 20:57:43
User entered 'Day 6'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:32:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-06T09:36:21', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '0b0fc691-a81b-4388-b679-186442c03f6c' User entered 'None (0)'	System	06 Sep 2020 14:36:53
	System	06 Sep 2020 14:36:53

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:32:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-06T09:36:24', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '0b0fc691-a81b-4388-b679-186442c03f6c' User entered 'None (0)'	System	06 Sep 2020 14:36:53
	System	06 Sep 2020 14:36:53

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:32:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-06T09:36:33', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '0b0fc691-a81b-4388-b679-186442c03f6c'	System	06 Sep 2020 14:36:53
User entered 'No interference with activity (1)'	System	06 Sep 2020 14:36:53

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:32:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-06T09:36:37', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '0b0fc691-a81b-4388-b679-186442c03f6c' User entered 'None (0)'	System	06 Sep 2020 14:36:53
	System	06 Sep 2020 14:36:53

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:32:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-06T09:36:39', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '0b0fc691-a81b-4388-b679-186442c03f6c' User entered 'None (0)'	System	06 Sep 2020 14:36:53
	System	06 Sep 2020 14:36:53

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:32:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-06T09:36:44', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '0b0fc691-a81b-4388-b679-186442c03f6c' User entered 'None (0)'	System	06 Sep 2020 14:36:53
	System	06 Sep 2020 14:36:53

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-06T09:36:47', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '0b0fc691-a81b-4388-b679-186442c03f6c' User entered 'No (N)'	System	06 Sep 2020 14:36:53
	System	06 Sep 2020 14:36:53

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-06T09:36:49', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '0b0fc691-a81b-4388-b679-186442c03f6c' User entered '06 Sep 2020 09:36'	System	06 Sep 2020 14:36:53
	System	06 Sep 2020 14:36:53

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
Data entry locked.	System	31 Aug 2020 20:57:43
User entered 'Day 7'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:32:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-07T09:51:15', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'f8416add-3b01-4084-b2ca-e0ca6f235d38' User entered 'None (0)'	System	07 Sep 2020 14:51:39
	System	07 Sep 2020 14:51:39

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:32:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-07T09:51:18', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'f8416add-3b01-4084-b2ca-e0ca6f235d38' User entered 'None (0)'	System	07 Sep 2020 14:51:39
	System	07 Sep 2020 14:51:39

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:32:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-07T09:51:22', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'f8416add-3b01-4084-b2ca-e0ca6f235d38'	System	07 Sep 2020 14:51:39
User entered 'No interference with activity (1)'	System	07 Sep 2020 14:51:39

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:32:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-07T09:51:25', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'f8416add-3b01-4084-b2ca-e0ca6f235d38' User entered 'None (0)'	System	07 Sep 2020 14:51:39
	System	07 Sep 2020 14:51:39

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:32:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-07T09:51:28', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'f8416add-3b01-4084-b2ca-e0ca6f235d38' User entered 'None (0)'	System	07 Sep 2020 14:51:39
	System	07 Sep 2020 14:51:39

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:32:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-07T09:51:31', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'f8416add-3b01-4084-b2ca-e0ca6f235d38' User entered 'None (0)'	System	07 Sep 2020 14:51:39
	System	07 Sep 2020 14:51:39

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-07T09:51:35', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'f8416add-3b01-4084-b2ca-e0ca6f235d38' User entered 'No (N)'	System	07 Sep 2020 14:51:39
	System	07 Sep 2020 14:51:39

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-07T09:51:37', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'f8416add-3b01-4084-b2ca-e0ca6f235d38' User entered '07 Sep 2020 09:51'	System	07 Sep 2020 14:51:39
	System	07 Sep 2020 14:51:39

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 20:57:43

US3862098

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
Data entry locked.	System	06 Sep 2020 14:36:53
User entered 'Day 8'	System	06 Sep 2020 14:36:53

US3862098

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 12 Aug 2021 13:32:46

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-08T09:53:48', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'bf59cdde-c0e5-45bd-8514-f7429901c524'	System	08 Sep 2020 14:53:57
User entered 'No interference with activity (1)'	System	08 Sep 2020 14:53:57

US3862098

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 12 Aug 2021 13:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-08T09:53:52', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'bf59cdde-c0e5-45bd-8514-f7429901c524' User entered '08 Sep 2020 09:53'	System	08 Sep 2020 14:53:57
	System	08 Sep 2020 14:53:57

US3862098

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 12 Aug 2021 13:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '07 Sep 2020 12:00'	System	06 Sep 2020 14:36:53

US3862098

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 12 Aug 2021 13:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '08 Sep 2020 11:59'	System	06 Sep 2020 14:36:53

US3862098

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
Data entry locked.	System	07 Sep 2020 14:51:39
User entered 'Day 9'	System	07 Sep 2020 14:51:39

US3862098

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 12 Aug 2021 13:32:46

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-09T10:42:46', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '6e164e2d-c5e5-48f5-af88-269e48cdc625'	System	09 Sep 2020 15:42:51
User entered 'None (0)'	System	09 Sep 2020 15:42:51

US3862098

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 12 Aug 2021 13:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-09T10:42:48', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '6e164e2d-c5e5-48f5-af88-269e48cdc625' User entered '09 Sep 2020 10:42'	System	09 Sep 2020 15:42:51
	System	09 Sep 2020 15:42:51

US3862098

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 12 Aug 2021 13:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 14:51:39

US3862098

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 12 Aug 2021 13:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 14:51:39

US3862098

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
Data entry locked.	System	06 Sep 2020 14:36:53
User entered 'Day 8'	System	06 Sep 2020 14:36:53

US3862098

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-08T09:53:57', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'ffd2a267-89b8-472a-bdb9-c18dd3f71b67'	System	08 Sep 2020 14:54:03
User entered 'No (N)'	System	08 Sep 2020 14:54:03

US3862098

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-08T09:54:01', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'ffd2a267-89b8-472a-bdb9-c18dd3f71b67' User entered '08 Sep 2020 09:54'	System	08 Sep 2020 14:54:03
	System	08 Sep 2020 14:54:03

US3862098

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '07 Sep 2020 12:00'	System	06 Sep 2020 14:36:53

US3862098

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '08 Sep 2020 11:59'	System	06 Sep 2020 14:36:53

US3862098

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
Data entry locked.	System	07 Sep 2020 14:51:39
User entered 'Day 9'	System	07 Sep 2020 14:51:39

US3862098

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-09T10:52:41', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '2bed2f49-e97a-40a8-aa6e-9fd6d29c4791'	System	09 Sep 2020 15:52:48
User entered 'No (N)'	System	09 Sep 2020 15:52:48

US3862098

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:32:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-09-09T10:52:46', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '2bed2f49-e97a-40a8-aa6e-9fd6d29c4791' User entered '09 Sep 2020 10:52'	System	09 Sep 2020 15:52:48
	System	09 Sep 2020 15:52:48

US3862098

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:32:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 14:51:39

US3862098

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:32:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 14:51:39

US3862098

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Yes (Y)'	Chanei Henry (b) (4)	09 Sep 2020 21:16:22
	(b) (4)	

US3862098

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '9 Sep 2020'	Chanei Henry (b) (4)	09 Sep 2020 21:16:22
	(b) (4)	

US3862098

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Chanei Henry (b) (4)	09 Sep 2020 21:16:22
	(b) (4)	

US3862098

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered empty.	Chanei Henry (b) (4)	09 Sep 2020 21:16:22
	(b) (4)	

US3862098

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Yes (Y)'	Chanei Henry (b) (4)	09 Sep 2020 21:16:29
	(b) (4)	

US3862098

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User entered 'I'	System	09 Sep 2020 21:16:29

US3862098

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	15 Sep 2020 23:36:18
	(b) (4)	

US3862098

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '14 Sep 2020'	Sandra Francisco (b) (4)	15 Sep 2020 23:36:18
	(b) (4)	

US3862098

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Sandra Francisco (b) (4)	15 Sep 2020 23:36:18
	(b) (4)	

US3862098

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	15 Sep 2020 23:36:18
	(b) (4)	

US3862098

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	25 Sep 2020 14:31:34

US3862098

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:46
User entered '1'	System	25 Sep 2020 14:31:34

US3862098

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	25 Sep 2020 21:34:18
	(b) (4)	

US3862098

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 06:33:54
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Safety Call Day 22 was completed out of window. A protocol deviation will be filled in source documentation. Please advise if further action is needed.' (Site from System).	Sandra Francisco (b) (4) (b) (4)	25 Sep 2020 21:34:21
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	25 Sep 2020 21:34:18
User entered '25 Sep 2020'	Sandra Francisco (b) (4) (b) (4)	25 Sep 2020 21:34:18

US3862098

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Sandra Francisco (b) (4)	25 Sep 2020 21:34:18
	(b) (4)	

US3862098

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	25 Sep 2020 21:34:18
	(b) (4)	

US3862098

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	30 Sep 2020 16:37:21
	(b) (4)	

US3862098

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:42
User entered '1'	System	30 Sep 2020 16:37:21

US3862098

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User closed query 'Per CDM: Response noted; Please update the field when available and route back to DM only after completing this form. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 09:10:21
Query 'Per CDM: Response noted; Please update the field when available and route back to DM only after completing this form. ' answered with 'Completed' (Site from DM).	Sandra Francisco (b) (4) (b) (4)	16 Oct 2020 18:07:47
User entered 'Yes (Y)' reason for change: Data Entry Error	Sandra Francisco (b) (4) (b) (4)	16 Oct 2020 18:06:45
User opened query 'Per CDM: Response noted; Please update the field when available and route back to DM only after completing this form. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 08:52:45
Query 'Per CDM: Response noted; Please update the field when available and route back to DM after completing this form.' canceled (Site from DM).		07 Oct 2020 08:52:38
User opened query 'Per CDM: Response noted; Please update the field when available and route back to DM after completing this form.' (Site from DM).		07 Oct 2020 08:50:17
User closed query 'Data is required. Please complete.' (Site from System).		07 Oct 2020 08:49:37
Query 'Data is required. Please complete.' answered with 'Visit is rescheduled within window. Will enter data once it is available. ' (Site from System).	Sandra Francisco (b) (4) (b) (4)	30 Sep 2020 16:42:39
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 16:42:07
User entered empty; reason for change Data Entry Error	Sandra Francisco (b) (4) (b) (4)	30 Sep 2020 16:42:07
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	30 Sep 2020 16:37:35

US3862098

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '02 Oct 2020' reason for change: Data Entry Error	Sandra Francisco (b) (4)	16 Oct 2020 18:06:45
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sandra Francisco (b) (4)	30 Sep 2020 16:42:07
	(b) (4)	
User entered '29 Sep 2020'	Sandra Francisco (b) (4)	30 Sep 2020 16:37:35
	(b) (4)	

US3862098

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Sandra Francisco (b) (4)	16 Oct 2020 18:06:45
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sandra Francisco (b) (4)	30 Sep 2020 16:42:07
	(b) (4)	
User entered 'Clinic (Clinic)'	Sandra Francisco (b) (4)	30 Sep 2020 16:37:35
	(b) (4)	

US3862098

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User entered 'VISIT2'	System	16 Oct 2020 18:06:45
User entered empty.	System	30 Sep 2020 16:42:07
User entered 'VISIT2'	System	30 Sep 2020 16:37:35

US3862098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User accepted default value 'Pre-Dose (PREDOSE)'	Sandra Francisco (b) (4) (b) (4)	30 Sep 2020 16:38:35

US3862098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User closed query 'Per CDM: Response noted; Please update the field when available and route back to DM after completing this form. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:09:14
Query 'Per CDM: Response noted; Please update the field when available and route back to DM after completing this form. ' answered with 'Data Corrected' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 16:48:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 16:47:24
User opened query 'Per CDM: Response noted; Please update the field when available and route back to DM after completing this form. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 08:51:23
User closed query 'Data is required. Please complete.' (Site from System).		07 Oct 2020 08:50:58
Query 'Data is required. Please complete.' answered with 'Visit is rescheduled within window. Will enter data once it is available. ' (Site from System).	Sandra Francisco (b) (4) (b) (4)	30 Sep 2020 16:43:29
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 16:43:26
User entered empty; reason for change Data Entry Error	Sandra Francisco (b) (4) (b) (4)	30 Sep 2020 16:43:26
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	30 Sep 2020 16:38:35

US3862098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '2 Oct 2020' reason for change: Data Entry Error	Shetel Anassi (b) (4)	20 Oct 2020 16:47:24
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sandra Francisco (b) (4)	30 Sep 2020 16:43:26
	(b) (4)	
User entered '29 Sep 2020'	Sandra Francisco (b) (4)	30 Sep 2020 16:38:35
	(b) (4)	

US3862098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '13:34' reason for change: Data Entry Error	Shetel Anassi (b) (4)	20 Oct 2020 16:47:24
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sandra Francisco (b) (4)	30 Sep 2020 16:43:26
	(b) (4)	
User entered '12:32' reason for change: Data Entry Error	Sandra Francisco (b) (4)	30 Sep 2020 16:38:57
	(b) (4)	
User entered '12:40'	Sandra Francisco (b) (4)	30 Sep 2020 16:38:35
	(b) (4)	

US3862098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User entered '2 Oct 2020 13:34'	System	20 Oct 2020 16:47:24
User entered empty.	System	30 Sep 2020 16:43:26
User entered '29 Sep 2020 12:32'	System	30 Sep 2020 16:38:57
User entered '29 Sep 2020 12:40'	System	30 Sep 2020 16:38:35

US3862098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '098.5' F reason for change: Data Entry Error	Shetel Anassi (b) (4)	20 Oct 2020 16:47:24
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sandra Francisco (b) (4)	30 Sep 2020 16:43:26
	(b) (4)	
User entered '98.3' F	Sandra Francisco (b) (4)	30 Sep 2020 16:38:35
	(b) (4)	

US3862098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Other (Other)' reason for change: Data Entry Error	Shetel Anassi (b) (4)	20 Oct 2020 16:47:24
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sandra Francisco (b) (4)	30 Sep 2020 16:43:26
	(b) (4)	
User entered 'Other (Other)'	Sandra Francisco (b) (4)	30 Sep 2020 16:38:35
	(b) (4)	

US3862098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Temporal' reason for change: Data Entry Error	Shetel Anassi (b) (4)	20 Oct 2020 16:47:24
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sandra Francisco (b) (4)	30 Sep 2020 16:43:26
	(b) (4)	
User entered 'Temporal'	Sandra Francisco (b) (4)	30 Sep 2020 16:38:35
	(b) (4)	

US3862098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '072' reason for change: Data Entry Error	Shetel Anassi (b) (4)	20 Oct 2020 16:47:24
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sandra Francisco (b) (4)	30 Sep 2020 16:43:26
	(b) (4)	
User entered '72'	Sandra Francisco (b) (4)	30 Sep 2020 16:38:35
	(b) (4)	

US3862098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User entered 'bpm'	System	20 Oct 2020 16:47:24
User entered empty.	System	30 Sep 2020 16:43:26
User entered 'bpm'	System	30 Sep 2020 16:38:35

US3862098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '016' reason for change: Data Entry Error	Shetel Anassi (b) (4)	20 Oct 2020 16:47:24
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sandra Francisco (b) (4)	30 Sep 2020 16:43:26
	(b) (4)	
User entered '12'	Sandra Francisco (b) (4)	30 Sep 2020 16:38:35
	(b) (4)	

US3862098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User entered 'breaths/min'	System	20 Oct 2020 16:47:24
User entered empty.	System	30 Sep 2020 16:43:26
User entered 'breaths/min'	System	30 Sep 2020 16:38:35

US3862098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '167' reason for change: Data Entry Error	Shetel Anassi (b) (4)	20 Oct 2020 16:47:24
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sandra Francisco (b) (4)	30 Sep 2020 16:43:26
	(b) (4)	
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	30 Sep 2020 16:38:57
Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	30 Sep 2020 16:38:57
User entered '162' reason for change: Data Entry Error	Sandra Francisco (b) (4)	30 Sep 2020 16:38:57
	(b) (4)	
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	30 Sep 2020 16:38:35
User entered '1'	Sandra Francisco (b) (4)	30 Sep 2020 16:38:35
	(b) (4)	

US3862098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User entered 'mmHg'	System	20 Oct 2020 16:47:24
User entered empty.	System	30 Sep 2020 16:43:26
User entered 'mmHg'	System	30 Sep 2020 16:38:35

US3862098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered '096' reason for change: Data Entry Error	Shetel Anassi (b) (4)	20 Oct 2020 16:47:24
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sandra Francisco (b) (4)	30 Sep 2020 16:43:26
	(b) (4)	
User closed query 'Diastolic blood pressure is greater than Systolic blood pressure. Please correct.' (Site from System).	System	30 Sep 2020 16:38:57
Query 'Diastolic blood pressure is greater than Systolic blood pressure. Please correct.' answered by data change (Site from System).	System	30 Sep 2020 16:38:57
User opened query 'Diastolic blood pressure is greater than Systolic blood pressure. Please correct.' (Site from System).	System	30 Sep 2020 16:38:35
User entered '97'	Sandra Francisco (b) (4)	30 Sep 2020 16:38:35
	(b) (4)	

US3862098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User entered 'mmHg'	System	20 Oct 2020 16:47:24
User entered empty.	System	30 Sep 2020 16:43:26
User entered 'mmHg'	System	30 Sep 2020 16:38:35

US3862098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User accepted default value 'Post-Dose (POSTDOSE)'	Sandra Francisco (b) (4) (b) (4)	30 Sep 2020 16:38:35

US3862098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User closed query 'Per CDM: Response noted; Please update the field when available and route back to DM after completing this form. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:09:24
Query 'Per CDM: Response noted; Please update the field when available and route back to DM after completing this form. ' answered with 'Discontinuation of treatment. No VS needed to assess.' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 16:49:28
User entered 'No (N)' reason for change: Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 16:48:57
User opened query 'Per CDM: Response noted; Please update the field when available and route back to DM after completing this form. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 08:51:37
User closed query 'Data is required. Please complete.' (Site from System).		07 Oct 2020 08:51:28
Query 'Data is required. Please complete.' answered with 'Visit is rescheduled within window. Will enter data once it is available. ' (Site from System).	Sandra Francisco (b) (4) (b) (4)	30 Sep 2020 16:42:48
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 16:41:52
User entered empty; reason for change Data Entry Error	Sandra Francisco (b) (4) (b) (4)	30 Sep 2020 16:41:52
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	30 Sep 2020 16:38:35

US3862098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 16:41:52
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 16:38:35
User entered empty.	Sandra Francisco (b) (4)	30 Sep 2020 16:38:35
	(b) (4)	

US3862098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 16:41:52
Query 'Data is required. Please provide.' answered by System data change (Site from System).		30 Sep 2020 16:41:52
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 16:38:35
User entered empty.	Sandra Francisco (b) (4)	30 Sep 2020 16:38:35
	(b) (4)	

US3862098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User entered empty.	System	30 Sep 2020 16:38:35

US3862098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 16:41:52
Query 'Data is required. Please provide.' answered by System data change (Site from System).		30 Sep 2020 16:41:52
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 16:38:35
User entered empty.	Sandra Francisco (b) (4)	30 Sep 2020 16:38:35
	(b) (4)	

US3862098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	30 Sep 2020 16:38:35
	(b) (4)	

US3862098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	30 Sep 2020 16:38:35
	(b) (4)	

US3862098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:39:42
User closed query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 16:41:52
Query 'Data is required. Please provide.' answered by System data change (Site from System).		30 Sep 2020 16:41:52
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 16:38:35
User entered empty.	Sandra Francisco (b) (4) (b) (4)	30 Sep 2020 16:38:35

US3862098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User entered empty.	System	30 Sep 2020 16:38:35

US3862098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 16:41:52
Query 'Data is required. Please provide.' answered by System data change (Site from System).		30 Sep 2020 16:41:52
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 16:38:35
User entered empty.	Sandra Francisco (b) (4)	30 Sep 2020 16:38:35
	(b) (4)	

US3862098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User entered empty.	System	30 Sep 2020 16:38:35

US3862098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 16:41:52
Query 'Data is required. Please provide.' answered by System data change (Site from System).		30 Sep 2020 16:41:52
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 16:38:35
User entered empty.	Sandra Francisco (b) (4)	30 Sep 2020 16:38:35
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User entered empty.	System	30 Sep 2020 16:38:35

US3862098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:39:42
User closed query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 16:41:52
Query 'Data is required. Please provide.' answered by System data change (Site from System).		30 Sep 2020 16:41:52
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 16:38:35
User entered empty.	Sandra Francisco (b) (4) (b) (4)	30 Sep 2020 16:38:35

US3862098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User entered empty.	System	30 Sep 2020 16:38:35

US3862098

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:32:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	02 Oct 2020 20:32:29

US3862098

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:32:46

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered '2 Oct 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	02 Oct 2020 20:32:29

US3862098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'No (N)'	Coni Cheesman (b) (4)	05 Oct 2020 21:53:04
	(b) (4)	

US3862098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Other (OTHER)'	Coni Cheesman (b) (4)	05 Oct 2020 21:53:04
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:39:42
User entered 'AE #1: medically attended newly diagnosed HTN.	Sandra Francisco (b) (4) (b) (4)	05 Oct 2020 21:59:07
PI and medical monitor determined subject is no longer eligible for dose 2 but should continue in study for safety and efficacy assessments.' reason for change: Data Entry Error		
User entered empty.	Coni Cheesman (b) (4) (b) (4)	05 Oct 2020 21:53:04

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User entered empty.	System	05 Oct 2020 21:53:04

US3862098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	05 Oct 2020 21:53:04
	(b) (4)	

US3862098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	05 Oct 2020 21:53:04
	(b) (4)	

US3862098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User entered empty.	System	05 Oct 2020 21:53:04

US3862098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	05 Oct 2020 21:53:04
	(b) (4)	

US3862098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User entered empty.	System	05 Oct 2020 21:53:04

US3862098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User entered empty.	System	05 Oct 2020 21:53:04

US3862098

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	02 Oct 2020 20:32:44

US3862098

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered '2 Oct 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	02 Oct 2020 20:32:44

US3862098

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered '14:45'	(b) (4) Carrie Kibler (b) (4) (b) (4)	02 Oct 2020 20:32:44

US3862098

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User entered '2 Oct 2020 14:45'	System	02 Oct 2020 20:32:44

US3862098

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:32:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered '2 Oct 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	02 Oct 2020 20:32:57

US3862098

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:32:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Carrie Kibler (b) (4) (b) (4)	02 Oct 2020 20:32:57

US3862098

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:32:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	02 Oct 2020 20:32:57

US3862098

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:32:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	02 Oct 2020 20:32:57

US3862098

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User entered empty.	System	02 Oct 2020 20:32:57

US3862098

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:32:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Carrie Kibler (b) (4) (b) (4)	02 Oct 2020 20:32:57

US3862098

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:32:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	02 Oct 2020 20:32:57

US3862098

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:32:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered '14:30'	(b) (4) Carrie Kibler (b) (4) (b) (4)	02 Oct 2020 20:32:57

US3862098

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User entered '2 Oct 2020 14:30'	System	02 Oct 2020 20:32:57

US3862098

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	02 Oct 2020 20:33:30
	(b) (4)	

US3862098

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User entered '1'	System	02 Oct 2020 20:33:30

US3862098

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Yes (Y)'	Shetel Anassi (b) (4)	12 Oct 2020 15:03:16
	(b) (4)	

US3862098

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered '06 Oct 2020'	(b) (4) Shetel Anassi (b) (4)	12 Oct 2020 15:03:16
	(b) (4)	

US3862098

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Shetel Anassi (b) (4)	12 Oct 2020 15:03:16
	(b) (4)	

US3862098

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered empty.	Shetel Anassi (b) (4)	12 Oct 2020 15:03:16
	(b) (4)	

US3862098

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Yes (Y)'	Shetel Anassi (b) (4)	12 Oct 2020 15:03:25
	(b) (4)	

US3862098

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User entered '1'	System	12 Oct 2020 15:03:25

US3862098

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	12 Oct 2020 21:45:13
	(b) (4)	

US3862098

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:39:42
User entered '16 Oct 2020' reason for change: New Information	Sandra Francisco (b) (4) (b) (4)	16 Oct 2020 19:30:08
User entered '12 Oct 2020'	Sandra Francisco (b) (4) (b) (4)	12 Oct 2020 21:45:13

US3862098

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Sandra Francisco (b) (4)	12 Oct 2020 21:45:13
	(b) (4)	

US3862098

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	12 Oct 2020 21:45:13
	(b) (4)	

US3862098

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	26 Oct 2020 22:23:08

US3862098

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User entered 'I'	System	26 Oct 2020 22:23:08

US3862098

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:02:49
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	27 Oct 2020 15:56:21

US3862098

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:02:49
User entered '23 Oct 2020'	Carrie Kibler (b) (4) (b) (4)	27 Oct 2020 15:56:21

US3862098

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:02:49
User entered 'Contact Not Made (CONTACT NOT MADE)'	Carrie Kibler (b) (4) (b) (4)	27 Oct 2020 15:56:21

US3862098

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:02:49
User entered 'Subject was called the 23rd and 26th of October multiple times. He told us to call him back later a couple of times. He never returned our phone calls or texts or answered again.'	Carrie Kibler (b) (4) (b) (4)	27 Oct 2020 15:56:21

US3862098

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:02:58
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	27 Oct 2020 15:56:34

US3862098

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User entered 'I'	System	27 Oct 2020 15:56:34

US3862098

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:23
User entered 'No (N)'	(b) (4)	
	Chanei Henry (b) (4)	25 Mar 2021 21:02:35
	(b) (4)	

US3862098

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:23
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	25 Mar 2021 21:02:35

US3862098

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:23
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	25 Mar 2021 21:02:35

US3862098

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User entered 'VISIT3'	System	25 Mar 2021 21:02:35

US3862098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:23
User entered 'No (N)'	(b) (4)	
	Chanei Henry (b) (4)	25 Mar 2021 21:02:49
	(b) (4)	

US3862098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:23
User entered empty.	(b) (4)	
	Chanei Henry (b) (4)	25 Mar 2021 21:02:49
	(b) (4)	

US3862098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:23
User entered empty.	(b) (4)	
	Chanei Henry (b) (4)	25 Mar 2021 21:02:49
	(b) (4)	

US3862098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User entered empty.	System	25 Mar 2021 21:02:49

US3862098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:23
User entered empty.	(b) (4)	
	Chanei Henry (b) (4)	25 Mar 2021 21:02:49
	(b) (4)	

US3862098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:23
User entered empty.	(b) (4)	
	Chanei Henry (b) (4)	25 Mar 2021 21:02:49
	(b) (4)	

US3862098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:23
User entered empty.	(b) (4)	
	Chanei Henry (b) (4)	25 Mar 2021 21:02:49
	(b) (4)	

US3862098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:23
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	25 Mar 2021 21:02:49

US3862098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User entered empty.	System	25 Mar 2021 21:02:49

US3862098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:23
User entered empty.	(b) (4)	
	Chanei Henry (b) (4)	25 Mar 2021 21:02:49
	(b) (4)	

US3862098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User entered empty.	System	25 Mar 2021 21:02:49

US3862098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:23
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	25 Mar 2021 21:02:49

US3862098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User entered empty.	System	25 Mar 2021 21:02:49

US3862098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:23
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	25 Mar 2021 21:02:49

US3862098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User entered empty.	System	25 Mar 2021 21:02:49

US3862098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47

US3862098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47

US3862098

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:32:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:23
User entered 'No (N)'	(b) (4)	
	Chanei Henry (b) (4)	25 Mar 2021 21:02:54
	(b) (4)	

US3862098

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:32:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:23
User entered empty.	(b) (4)	
	Chanei Henry (b) (4)	25 Mar 2021 21:02:54
	(b) (4)	

US3862098

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:23
User entered 'No (N)'	(b) (4)	
	Chanei Henry (b) (4)	25 Mar 2021 21:02:59
	(b) (4)	

US3862098

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:23
User entered empty.	(b) (4)	
	Chanei Henry (b) (4)	25 Mar 2021 21:02:59
	(b) (4)	

US3862098

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:23
User entered empty.	(b) (4)	
	Chanei Henry (b) (4)	25 Mar 2021 21:02:59
	(b) (4)	

US3862098

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User entered empty.	System	25 Mar 2021 21:02:59

US3862098

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:42
	(b) (4)	
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	01 Dec 2020 16:26:36
	(b) (4)	

US3862098

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:01:47
User entered '1'	System	01 Dec 2020 16:26:36

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
Data entry locked.	System	31 Aug 2020 20:57:43
User entered 'Day 64'	System	31 Aug 2020 20:57:43

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-11-02T11:30:40', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '45662418-5e54-4ca7-88db-c4d60dc22800'	System	02 Nov 2020 17:31:01
User entered 'No (N)'	System	02 Nov 2020 17:31:01

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-11-02T11:30:45', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '45662418-5e54-4ca7-88db-c4d60dc22800'	System	02 Nov 2020 17:31:01
User entered 'No (N)'	System	02 Nov 2020 17:31:01

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-11-02T11:30:57', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '45662418-5e54-4ca7-88db-c4d60dc22800' User entered '02 Nov 2020 11:30:57'	System	02 Nov 2020 17:31:01
	System	02 Nov 2020 17:31:01

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
Data entry locked.	System	31 Aug 2020 20:57:43
User entered '31 Oct 2020 00:01'	System	31 Aug 2020 20:57:43

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:38:59
Data entry locked.	System	31 Aug 2020 20:57:43
User entered '04 Nov 2020 23:59'	System	31 Aug 2020 20:57:43

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24
Data entry locked.	System	31 Aug 2020 20:57:43
User entered 'Day 71'	System	31 Aug 2020 20:57:43

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24
Data entry locked.	System	31 Aug 2020 20:57:43
User entered '07 Nov 2020 00:01'	System	31 Aug 2020 20:57:43

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24
Data entry locked.	System	31 Aug 2020 20:57:43
User entered '11 Nov 2020 23:59'	System	31 Aug 2020 20:57:43

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24
Data entry locked.	System	31 Aug 2020 20:57:43
User entered 'Day 78'	System	31 Aug 2020 20:57:43

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24
Data entry locked.	System	31 Aug 2020 20:57:43
User entered '14 Nov 2020 00:01'	System	31 Aug 2020 20:57:43

US3862098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:16:24
Data entry locked.	System	31 Aug 2020 20:57:43
User entered '18 Nov 2020 23:59'	System	31 Aug 2020 20:57:43

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-12-23T11:59:38', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'b82eea15-88c0-4767-896d-a865f90b07cc' User entered 'No (N)'	System	23 Dec 2020 16:59:50
	System	23 Dec 2020 16:59:50

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-12-23T11:59:41', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'b82eea15-88c0-4767-896d-a865f90b07cc'	System	23 Dec 2020 16:59:50
User entered 'No (N)'	System	23 Dec 2020 16:59:50

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2020-12-23T11:59:45', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'b82eea15-88c0-4767-896d-a865f90b07cc' User entered '23 Dec 2020 11:59:45'	System	23 Dec 2020 16:59:50
	System	23 Dec 2020 16:59:50

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-01-06T11:38:41', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '4923bce4-3ce6-4d6c-a9ab-5daaf016ec82'	System	06 Jan 2021 17:38:52
User entered 'No (N)'	System	06 Jan 2021 17:38:52

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-01-06T11:38:45', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '4923bce4-3ce6-4d6c-a9ab-5daaf016ec82'	System	06 Jan 2021 17:38:52
User entered 'No (N)'	System	06 Jan 2021 17:38:52

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-01-06T11:38:49', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '4923bce4-3ce6-4d6c-a9ab-5daaf016ec82'	System	06 Jan 2021 17:38:52
User entered '06 Jan 2021 11:38:49'	System	06 Jan 2021 17:38:52

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-01-15T20:22:40', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'd6801410-99b6-4807-9961-322f13840f62'	System	16 Jan 2021 02:22:56
User entered 'No (N)'	System	16 Jan 2021 02:22:56

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-01-15T20:22:44', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'd6801410-99b6-4807-9961-322f13840f62'	System	16 Jan 2021 02:22:56
User entered 'No (N)'	System	16 Jan 2021 02:22:56

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-01-15T20:22:51', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'd6801410-99b6-4807-9961-322f13840f62'	System	16 Jan 2021 02:22:56
User entered '15 Jan 2021 20:22:51'	System	16 Jan 2021 02:22:56

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-01-20T17:08:44', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '4f2becae-7a4e-4cdb-96f4-055594ef3b60' User entered 'No (N)'	System	20 Jan 2021 23:08:56
	System	20 Jan 2021 23:08:56

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-01-20T17:08:49', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '4f2becae-7a4e-4cdb-96f4-055594ef3b60'	System	20 Jan 2021 23:08:56
User entered 'No (N)'	System	20 Jan 2021 23:08:56

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-01-20T17:08:52', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '4f2becae-7a4e-4cdb-96f4-055594ef3b60' User entered '20 Jan 2021 17:08:52'	System	20 Jan 2021 23:08:56
	System	20 Jan 2021 23:08:56

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-01-27T00:01:42', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '2440ac33-d6d5-4490-8f48-ded8ca5ad875' User entered 'No (N)'	System	27 Jan 2021 06:01:56
	System	27 Jan 2021 06:01:56

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-01-27T00:01:46', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '2440ac33-d6d5-4490-8f48-ded8ca5ad875' User entered 'No (N)'	System	27 Jan 2021 06:01:56
	System	27 Jan 2021 06:01:56

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-01-27T00:01:49', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '2440ac33-d6d5-4490-8f48-ded8ca5ad875' User entered '27 Jan 2021 00:01:49'	System	27 Jan 2021 06:01:56
	System	27 Jan 2021 06:01:56

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-02-06T18:01:01', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'b869862d-b83b-4144-a524-120ffcaa14f6'	System	07 Feb 2021 00:02:12
User entered 'No (N)'	System	07 Feb 2021 00:02:12

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-02-06T18:01:04', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'b869862d-b83b-4144-a524-120ffcaa14f6'	System	07 Feb 2021 00:02:12
User entered 'No (N)'	System	07 Feb 2021 00:02:12

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-02-06T18:01:07', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'b869862d-b83b-4144-a524-120ffcaa14f6'	System	07 Feb 2021 00:02:12
User entered '06 Feb 2021 18:01:07'	System	07 Feb 2021 00:02:12

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-02-10T00:33:09', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'ddab92b5-1019-409b-b366-1ff047522d70'	System	10 Feb 2021 06:33:18
User entered 'No (N)'	System	10 Feb 2021 06:33:18

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-02-10T00:33:12', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'ddab92b5-1019-409b-b366-1ff047522d70' User entered 'No (N)'	System	10 Feb 2021 06:33:18
	System	10 Feb 2021 06:33:18

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-02-10T00:33:15', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'ddab92b5-1019-409b-b366-1ff047522d70'	System	10 Feb 2021 06:33:18
User entered '10 Feb 2021 00:33:15'	System	10 Feb 2021 06:33:18

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-02-20T17:59:20', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'b193db8b-10bf-4afd-ad50-dedf8b5d9019'	System	20 Feb 2021 23:59:31
User entered 'No (N)'	System	20 Feb 2021 23:59:31

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-02-20T17:59:24', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'b193db8b-10bf-4afd-ad50-dedf8b5d9019'	System	20 Feb 2021 23:59:31
User entered 'No (N)'	System	20 Feb 2021 23:59:31

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-02-20T17:59:27', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'b193db8b-10bf-4afd-ad50-dedf8b5d9019' User entered '20 Feb 2021 17:59:27'	System	20 Feb 2021 23:59:31
	System	20 Feb 2021 23:59:31

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-02-28T11:59:41-07:00', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'b43fab22-e56b-4135-844f-fe5c0ff502f0'	System	28 Feb 2021 18:59:53
User entered 'No (N)'	System	28 Feb 2021 18:59:53

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-02-28T11:59:44-07:00', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'b43fab22-e56b-4135-844f-fe5c0ff502f0'	System	28 Feb 2021 18:59:53
User entered 'No (N)'	System	28 Feb 2021 18:59:53

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-02-28T11:59:48-07:00', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'b43fab22-e56b-4135-844f-fe5c0ff502f0'	System	28 Feb 2021 18:59:53
User entered '28 Feb 2021 18:59:48'	System	28 Feb 2021 18:59:53

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-03-05T17:58:03-07:00', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '97026e4b-db98-4389-833a-f75b733f2ec1' User entered 'No (N)'	System	06 Mar 2021 00:58:18
	System	06 Mar 2021 00:58:18

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-03-05T17:58:10-07:00', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '97026e4b-db98-4389-833a-f75b733f2ec1' User entered 'No (N)'	System	06 Mar 2021 00:58:18
	System	06 Mar 2021 00:58:18

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-03-05T17:58:14-07:00', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '97026e4b-db98-4389-833a-f75b733f2ec1' User entered '05 Mar 2021 17:58:14'	System	06 Mar 2021 00:58:18
	System	06 Mar 2021 00:58:18

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-03-13T18:06:24-06:00', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '25e2689d-b677-4749-8a96-62cd687104f1'	System	14 Mar 2021 00:08:04
User entered 'No (N)'	System	14 Mar 2021 00:08:04

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-03-13T18:06:27-06:00', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '25e2689d-b677-4749-8a96-62cd687104f1'	System	14 Mar 2021 00:08:04
User entered 'No (N)'	System	14 Mar 2021 00:08:04

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-03-13T18:06:30-06:00', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '25e2689d-b677-4749-8a96-62cd687104f1'	System	14 Mar 2021 00:08:04
User entered '13 Mar 2021 18:06:30'	System	14 Mar 2021 00:08:04

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-03-17T11:40:42-05:00', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '01bce8f4-cf1b-4b1d-bb3d-a45a6649e3e8'	System	19 Mar 2021 02:35:23
User entered 'No (N)'	System	19 Mar 2021 02:35:23

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-03-18T21:35:17-05:00', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '01bce8f4-cf1b-4b1d-bb3d-a45a6649e3e8'	System	19 Mar 2021 02:35:23
User entered 'No (N)'	System	19 Mar 2021 02:35:23

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-03-18T21:35:20-05:00', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '01bce8f4-cf1b-4b1d-bb3d-a45a6649e3e8'	System	19 Mar 2021 02:35:23
User entered '18 Mar 2021 21:35:20'	System	19 Mar 2021 02:35:23

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-03-24T00:28:37-05:00', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'fd66bdb2-7ab3-4ff4-9218-a1bb7e296f1f'	System	24 Mar 2021 05:29:00
User entered 'No (N)'	System	24 Mar 2021 05:29:00

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-03-24T00:28:55-05:00', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'fd66bdb2-7ab3-4ff4-9218-a1bb7e296f1f'	System	24 Mar 2021 05:29:00
User entered 'No (N)'	System	24 Mar 2021 05:29:00

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-03-24T00:28:59-05:00', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'fd66bdb2-7ab3-4ff4-9218-a1bb7e296f1f' User entered '24 Mar 2021 00:28:59'	System	24 Mar 2021 05:29:00
	System	24 Mar 2021 05:29:00

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-04-07T13:13:27-05:00', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '0e3c59e6-fbe3-4aea-b0d4-99f178469de9'	System	07 Apr 2021 18:13:42
User entered 'No (N)'	System	07 Apr 2021 18:13:42

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-04-07T13:13:30-05:00', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '0e3c59e6-fbe3-4aea-b0d4-99f178469de9'	System	07 Apr 2021 18:13:42
User entered 'No (N)'	System	07 Apr 2021 18:13:42

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-04-07T13:13:33-05:00', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '0e3c59e6-fbe3-4aea-b0d4-99f178469de9' User entered '07 Apr 2021 13:13:33'	System	07 Apr 2021 18:13:42
	System	07 Apr 2021 18:13:42

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-04-17T17:50:16-05:00', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '6a779c75-9002-4052-bb45-5ff15d79eeb9' User entered 'No (N)'	System	21 Apr 2021 05:25:10
	System	21 Apr 2021 05:25:10

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-04-17T17:50:20-05:00', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '6a779c75-9002-4052-bb45-5ff15d79eeb9'	System	21 Apr 2021 05:25:10
User entered 'No (N)'	System	21 Apr 2021 05:25:10

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-04-17T17:50:22-05:00', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '6a779c75-9002-4052-bb45-5ff15d79eeb9' User entered '17 Apr 2021 17:50:22'	System	21 Apr 2021 05:25:10
	System	21 Apr 2021 05:25:10

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-04-21T00:25:10-05:00', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'b23151a1-40b5-486b-8dd3-529bf72a1587'	System	21 Apr 2021 05:25:19
User entered 'No (N)'	System	21 Apr 2021 05:25:19

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-04-21T00:25:14-05:00', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'b23151a1-40b5-486b-8dd3-529bf72a1587'	System	21 Apr 2021 05:25:19
User entered 'No (N)'	System	21 Apr 2021 05:25:19

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-04-21T00:25:17-05:00', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: 'b23151a1-40b5-486b-8dd3-529bf72a1587'	System	21 Apr 2021 05:25:19
User entered '21 Apr 2021 00:25:17'	System	21 Apr 2021 05:25:19

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-04-30T12:24:02-05:00', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '942dbea0-6087-4546-b669-8662e6eec26c' User entered 'No (N)'	System	30 Apr 2021 17:24:19
	System	30 Apr 2021 17:24:19

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-04-30T12:24:12-05:00', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '942dbea0-6087-4546-b669-8662e6eec26c'	System	30 Apr 2021 17:24:19
User entered 'No (N)'	System	30 Apr 2021 17:24:19

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-04-30T12:24:14-05:00', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '942dbea0-6087-4546-b669-8662e6eec26c' User entered '30 Apr 2021 12:24:14'	System	30 Apr 2021 17:24:19
	System	30 Apr 2021 17:24:19

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '26 Oct 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '30 Oct 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '02 Nov 2022 00:01'	System	19 Nov 2020 21:16:24

US3862098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:16:24
Amendment Manager: User entered '06 Nov 2022 23:59'	System	19 Nov 2020 21:16:24

US3862098

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:32:46

[Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-02-28T20:16:42-07:00', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '64116a6b-f5ec-44b6-8e3b-1f1d86916c93'	System	01 Mar 2021 03:19:56
User entered 'No (N)'	System	01 Mar 2021 03:19:56

US3862098

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:32:46

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4689E5-3CC5-4FA4-866E-3545A5BD90A9)', Time: '2021-02-28T20:16:48-07:00', User OID: 'PatientReportedOutcome (US3862098)', ODM File OID: '64116a6b-f5ec-44b6-8e3b-1f1d86916c93' User entered '01 Mar 2021 03:16:48'	System	01 Mar 2021 03:19:56
	System	01 Mar 2021 03:19:56

US3862098

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:29:25
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:29:07
	(b) (4)	
User entered 'Yes (Y)'	Chanei Henry (b) (4)	01 Dec 2020 21:52:18
	(b) (4)	

US3862098

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:29:25
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:29:07
	(b) (4)	
User entered '30 Nov 2020'	Chanei Henry (b) (4)	01 Dec 2020 21:52:18
	(b) (4)	

US3862098

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:29:25
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:29:07
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Chanei Henry (b) (4)	01 Dec 2020 21:52:18

US3862098

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:29:25
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:29:07
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	(b) (4)	01 Dec 2020 21:52:23
Please review and reconcile.' (Site from System).		
User entered 'UNABLE TO REACH SUBJECT, PD completed' reason for change: Data Entry Error	Chanei Henry (b) (4)	01 Dec 2020 21:52:23
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	(b) (4)	01 Dec 2020 21:52:18
Please review and reconcile.' (Site from System).		
User entered empty.	Chanei Henry (b) (4)	01 Dec 2020 21:52:18
	(b) (4)	

US3862098

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:29:25
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:29:07
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	29 Dec 2020 15:48:20

US3862098

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:29:25
User entered '1'	System	29 Dec 2020 15:48:20

US3862098

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Dec 2020 19:08:25

US3862098

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '31 Dec 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Dec 2020 19:08:25

US3862098

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Dec 2020 19:08:25

US3862098

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Dec 2020 19:08:25

US3862098

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Dec 2020 19:08:30

US3862098

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User entered 'I'	System	31 Dec 2020 19:08:30

US3862098

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:27:41

US3862098

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:27:41

US3862098

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:27:41

US3862098

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:27:41

US3862098

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:27:52

US3862098

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User entered 'I'	System	27 Jan 2021 21:27:52

US3862098

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:32:21

US3862098

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:32:21

US3862098

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:32:21

US3862098

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 18:32:21

US3862098

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Mar 2021 18:33:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Mar 2021 18:33:07
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 18:33:07
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Mar 2021 18:32:57
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 18:32:57

US3862098

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User entered '1'	System	12 Mar 2021 18:33:07
User entered empty.	System	12 Mar 2021 18:32:57

US3862098

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	17 Mar 2021 18:15:22

US3862098

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '17 Mar 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	17 Mar 2021 18:15:22

US3862098

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Clinic (Clinic)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	17 Mar 2021 18:15:22

US3862098

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User entered 'VISIT4'	System	17 Mar 2021 18:15:22

US3862098

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Mar 2021 22:15:46

US3862098

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '17 Mar 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Mar 2021 22:15:46

US3862098

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '11:39'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Mar 2021 22:15:46

US3862098

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User entered '17 Mar 2021 11:39'	System	30 Mar 2021 22:15:46

US3862098

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered '98.4' F	Carrie Kibler (b) (4)	30 Mar 2021 22:15:46
	(b) (4)	

US3862098

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Other (Other)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Mar 2021 22:15:46

US3862098

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'temporal'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Mar 2021 22:15:46

US3862098

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '51'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Mar 2021 22:15:46

US3862098

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User entered 'bpm'	System	30 Mar 2021 22:15:46

US3862098

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '16'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Mar 2021 22:15:46

US3862098

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User entered 'breaths/min'	System	30 Mar 2021 22:15:46

US3862098

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '116'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Mar 2021 22:15:46

US3862098

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User entered 'mmHg'	System	30 Mar 2021 22:15:46

US3862098

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '66'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Mar 2021 22:15:46

US3862098

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User entered 'mmHg'	System	30 Mar 2021 22:15:46

US3862098

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39

US3862098

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39

US3862098

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:32:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	17 Mar 2021 18:15:27

US3862098

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:32:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '17 Mar 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	17 Mar 2021 18:15:27

US3862098

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	17 Mar 2021 18:15:37

US3862098

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '17 Mar 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	17 Mar 2021 18:15:37

US3862098

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '11:46'	(b) (4) Carrie Kibler (b) (4) (b) (4)	17 Mar 2021 18:15:37

US3862098

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User entered '17 Mar 2021 11:46'	System	17 Mar 2021 18:15:37

US3862098

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	17 Mar 2021 18:15:53

US3862098

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:39
User entered '1'	System	17 Mar 2021 18:15:53

US3862098

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:01
	(b) (4)	
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	27 Apr 2021 15:59:02
	(b) (4)	

US3862098

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:01
	(b) (4)	
User entered '23 Apr 2021'	Sandra Francisco (b) (4)	27 Apr 2021 15:59:02
	(b) (4)	

US3862098

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:01
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Sandra Francisco (b) (4)	27 Apr 2021 15:59:02
	(b) (4)	

US3862098

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:01
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	27 Apr 2021 15:59:02
	(b) (4)	

US3862098

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:01
	(b) (4)	
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	27 Apr 2021 15:59:07
	(b) (4)	

US3862098

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Apr 2021 15:59:07

US3862098

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

Form: Visit Date

Generated On: 12 Aug 2021 13:32:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	06 Jan 2021 16:40:12
	(b) (4)	

US3862098

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

Form: Visit Date

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '06 Jan 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 16:40:12

US3862098

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

Form: Visit Date

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Clinic (Clinic)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 16:40:12

US3862098

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

Form: Visit Date

Generated On: 12 Aug 2021 13:32:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User entered 'UNBLND_DECIDE'	System	06 Jan 2021 16:40:12

US3862098

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

Form: Unblinding

Generated On: 12 Aug 2021 13:32:46

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '06 Jan 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 16:40:30

US3862098

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

Form: Unblinding

Generated On: 12 Aug 2021 13:32:46

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '0'	(b) (4) Carrie Kibler (b) (4)	30 Mar 2021 22:15:53
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 07:41:53

US3862098

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

Form: Unblinding

Generated On: 12 Aug 2021 13:32:46

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User closed query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	07 Jan 2021 05:14:00
Query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' answered with 'subject did not receive the second dose due to a new adverse event at that time.' (Site from System).	Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 16:40:54
User opened query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	System	06 Jan 2021 16:40:30
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 16:40:30

US3862098

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

Form: Unblinding

Generated On: 12 Aug 2021 13:32:46

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) Carrie Kibler (b) (4)	30 Mar 2021 22:15:53
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 07:41:53

US3862098

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

Form: Unblinding

Generated On: 12 Aug 2021 13:32:46

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '06 Jan 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 16:40:30

US3862098

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

Form: Unblinding

Generated On: 12 Aug 2021 13:32:46

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered 'Placebo (Placebo)'	Carrie Kibler (b) (4)	06 Jan 2021 16:40:30
	(b) (4)	

US3862098

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

Form: Unblinding

Generated On: 12 Aug 2021 13:32:46

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 03:49:44
User entered 'Placebo (Placebo)'	Carrie Kibler (b) (4)	06 Jan 2021 16:40:30
	(b) (4)	

US3862098

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

Form: Unblinding

Generated On: 12 Aug 2021 13:32:46

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 03:49:44
User entered 'Placebo (Placebo)' reason for change:	Carrie Kibler (b) (4)	06 Jan 2021 21:39:18
New Information	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	06 Jan 2021 16:40:30
	(b) (4)	

US3862098

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

Form: Unblinding

Generated On: 12 Aug 2021 13:32:46

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 16:40:30

US3862098

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

Form: Unblinding

Generated On: 12 Aug 2021 13:32:46

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User entered 'I'	System	06 Jan 2021 21:39:18
User entered empty.	System	06 Jan 2021 16:40:30

US3862098

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

Form: Unblinding

Generated On: 12 Aug 2021 13:32:46

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User entered 'I'	System	06 Jan 2021 21:39:18
User entered empty.	System	06 Jan 2021 16:40:30

US3862098

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:32:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered missing code ND - Not Done.	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 21:42:28

US3862098

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:32:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered missing code ND - Not Done.	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 21:42:28

US3862098

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:32:46

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User entered empty.	System	06 Jan 2021 21:42:28
DataPoint set to visible.	System	06 Jan 2021 21:39:18

US3862098

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:32:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered missing code ND - Not Done.	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 21:42:28

US3862098

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:32:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered missing code ND - Not Done.	Carrie Kibler (b) (4)	06 Jan 2021 21:42:28
	(b) (4)	

US3862098

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:32:46

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User entered empty.	System	06 Jan 2021 21:42:28
DataPoint set to visible.	System	06 Jan 2021 21:39:18

US3862098

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User accepted default value 'Pre-Dose (PREDOSE)'	Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 21:42:28

US3862098

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 21:42:28

US3862098

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '06 Jan 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 21:42:28

US3862098

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	
User entered '09:43' reason for change: Data Entry Error	System	06 Jan 2021 21:45:17
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	Carrie Kibler (b) (4)	06 Jan 2021 21:45:17
User entered '12:14'	(b) (4)	
	System	06 Jan 2021 21:42:28
	Carrie Kibler (b) (4)	06 Jan 2021 21:42:28
	(b) (4)	

US3862098

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User entered '06 Jan 2021 09:43'	System	06 Jan 2021 21:45:17
User entered '06 Jan 2021 12:14'	System	06 Jan 2021 21:42:28

US3862098

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '97.5' F reason for change: Data Entry Error	(b) (4) Carrie Kibler (b) (4)	06 Jan 2021 21:45:17
User entered '97.7' F	(b) (4) Carrie Kibler (b) (4)	06 Jan 2021 21:42:28

US3862098

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Other (Other)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 21:42:28

US3862098

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered 'temporal'	Carrie Kibler (b) (4)	06 Jan 2021 21:42:28
	(b) (4)	

US3862098

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '45' reason for change: Data Entry Error	(b) (4)	
	Carrie Kibler (b) (4)	06 Jan 2021 21:45:17
User entered '55'	(b) (4)	
	Carrie Kibler (b) (4)	06 Jan 2021 21:42:28
	(b) (4)	

US3862098

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User entered 'bpm'	System	06 Jan 2021 21:42:28

US3862098

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '15'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 21:42:28

US3862098

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User entered 'breaths/min'	System	06 Jan 2021 21:42:28

US3862098

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '126' reason for change: Data Entry Error	(b) (4)	
	Carrie Kibler (b) (4)	06 Jan 2021 21:45:17
User entered '140'	(b) (4)	
	Carrie Kibler (b) (4)	06 Jan 2021 21:42:28
	(b) (4)	

US3862098

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User entered 'mmHg'	System	06 Jan 2021 21:42:28

US3862098

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '83' reason for change: Data Entry Error	(b) (4) Carrie Kibler (b) (4)	06 Jan 2021 21:45:17
User entered '80'	(b) (4) Carrie Kibler (b) (4)	06 Jan 2021 21:42:28

US3862098

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User entered 'mmHg'	System	06 Jan 2021 21:42:28

US3862098

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:32:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered missing code ND - Not Done.	(b) (4) Carrie Kibler (b) (4)	06 Jan 2021 21:42:28
	(b) (4)	

US3862098

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:32:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered missing code ND - Not Done.	(b) (4)	
	Carrie Kibler (b) (4)	06 Jan 2021 21:42:28
	(b) (4)	

US3862098

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:32:46

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User entered empty.	System	06 Jan 2021 21:42:28
DataPoint set to visible.	System	06 Jan 2021 21:39:18

US3862098

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User accepted default value 'Post-Dose (POSTDOSE)'	Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 21:46:12

US3862098

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 21:46:12

US3862098

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '06 Jan 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 21:46:12

US3862098

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '12:14'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 21:46:12

US3862098

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User entered '06 Jan 2021 12:14'	System	06 Jan 2021 21:46:12

US3862098

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '97.7' F	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 21:46:12

US3862098

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Other (Other)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 21:46:12

US3862098

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'temporal'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 21:46:12

US3862098

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '55'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 21:46:12

US3862098

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User entered 'bpm'	System	06 Jan 2021 21:46:12

US3862098

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '15'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 21:46:12

US3862098

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User entered 'breaths/min'	System	06 Jan 2021 21:46:12

US3862098

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '140'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 21:46:12

US3862098

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User entered 'mmHg'	System	06 Jan 2021 21:46:12

US3862098

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '80'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 21:46:12

US3862098

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User entered 'mmHg'	System	06 Jan 2021 21:46:12

US3862098

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

Form: Physical Examination

Generated On: 12 Aug 2021 13:32:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 21:39:29

US3862098

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

Form: Physical Examination

Generated On: 12 Aug 2021 13:32:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	06 Jan 2021 21:39:29
	(b) (4)	

US3862098

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

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 21:40:49

US3862098

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

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 21:40:49

US3862098

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

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	06 Jan 2021 21:40:49
	(b) (4)	

US3862098

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

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User entered 'mRNA-1273'	System	06 Jan 2021 21:40:49
DataPoint set to visible.	System	06 Jan 2021 21:39:18

US3862098

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

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '06 Jan 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 21:40:49

US3862098

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

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '11:30'	(b) (4)	
	Carrie Kibler (b) (4)	06 Jan 2021 21:40:49
	(b) (4)	

US3862098

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

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User entered '06 Jan 2021 11:30'	System	06 Jan 2021 21:40:49

US3862098

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

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Left Arm (LEFT ARM)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 21:40:49

US3862098

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

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User entered 'ONCE'	System	06 Jan 2021 21:40:49

US3862098

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

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User entered 'INTRAMUSCULAR'	System	06 Jan 2021 21:40:49

US3862098

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 16:41:07

US3862098

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '06 Jan 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 16:41:07

US3862098

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered '10:21'	Carrie Kibler (b) (4)	06 Jan 2021 16:41:07
	(b) (4)	

US3862098

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User entered '06 Jan 2021 10:21'	System	06 Jan 2021 16:41:07

US3862098

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:32:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 16:41:19

US3862098

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:32:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '06 Jan 2021'	(b) (4)	
	Carrie Kibler (b) (4)	06 Jan 2021 16:41:19
	(b) (4)	

US3862098

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:32:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered '10:15'	Carrie Kibler (b) (4)	06 Jan 2021 16:41:19
	(b) (4)	

US3862098

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User entered '06 Jan 2021 10:15'	System	06 Jan 2021 16:41:19

US3862098

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

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 21:45:28

US3862098

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

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User entered 'I'	System	06 Jan 2021 21:45:28

US3862098

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Yes (Y)'	(b) (4)	13 Jan 2021 22:15:50
	Thea Marie Cordero	
	(b) (4)	

US3862098

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered '13 Jan 2021'	Thea Marie Cordero	13 Jan 2021 22:15:50
	(b) (4)	

US3862098

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
	Thea Marie Cordero	13 Jan 2021 22:15:50
	(b) (4)	

US3862098

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered empty.	Thea Marie Cordero	13 Jan 2021 22:15:50
	(b) (4)	

US3862098

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Yes (Y)'	(b) (4)	13 Jan 2021 22:15:55
	Thea Marie Cordero	
	(b) (4)	

US3862098

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User entered 'I'	System	13 Jan 2021 22:15:55

US3862098

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User entered 'I'	System	13 Jan 2021 22:15:55
DataPoint set to visible.	System	13 Jan 2021 22:15:55

US3862098

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	03 Feb 2021 16:51:30
	(b) (4)	

US3862098

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:46

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '03 Feb 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Feb 2021 16:51:30

US3862098

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered 'Clinic (Clinic)'	Carrie Kibler (b) (4)	03 Feb 2021 16:51:30
	(b) (4)	

US3862098

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User entered 'OLD29'	System	03 Feb 2021 16:51:30

US3862098

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User accepted default value 'Pre-Dose (PREDOSE)'	Carrie Kibler (b) (4)	03 Feb 2021 16:52:53

US3862098

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Feb 2021 16:52:53

US3862098

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '03 Feb 2021'	(b) (4)	
	Carrie Kibler (b) (4)	03 Feb 2021 16:52:53
	(b) (4)	

US3862098

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '10:03'	(b) (4)	
	Carrie Kibler (b) (4)	03 Feb 2021 16:52:53
	(b) (4)	

US3862098

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User entered '03 Feb 2021 10:03'	System	03 Feb 2021 16:52:53

US3862098

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered '97.8' F	Carrie Kibler (b) (4)	03 Feb 2021 16:52:53
	(b) (4)	

US3862098

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Other (Other)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Feb 2021 16:52:53

US3862098

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered 'Temporal'	Carrie Kibler (b) (4)	03 Feb 2021 16:52:53
	(b) (4)	

US3862098

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '56'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Feb 2021 16:52:53

US3862098

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User entered 'bpm'	System	03 Feb 2021 16:52:53

US3862098

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered '15'	Carrie Kibler (b) (4)	03 Feb 2021 16:52:53
	(b) (4)	

US3862098

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User entered 'breaths/min'	System	03 Feb 2021 16:52:53

US3862098

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '115'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Feb 2021 16:52:53

US3862098

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User entered 'mmHg'	System	03 Feb 2021 16:52:53

US3862098

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '65'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Feb 2021 16:52:53

US3862098

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User entered 'mmHg'	System	03 Feb 2021 16:52:53

US3862098

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User accepted default value 'Post-Dose (POSTDOSE)'	Carrie Kibler (b) (4) (b) (4)	03 Feb 2021 17:39:45

US3862098

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Feb 2021 17:39:45

US3862098

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '03 Feb 2021'	(b) (4)	
	Carrie Kibler (b) (4)	03 Feb 2021 17:39:45
	(b) (4)	

US3862098

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered '11:37'	Carrie Kibler (b) (4)	03 Feb 2021 17:39:45
	(b) (4)	

US3862098

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User entered '03 Feb 2021 11:37'	System	03 Feb 2021 17:39:45

US3862098

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered '97.8' F	Carrie Kibler (b) (4)	03 Feb 2021 17:39:45
	(b) (4)	

US3862098

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered 'Other (Other)'	Carrie Kibler (b) (4)	03 Feb 2021 17:39:45
	(b) (4)	

US3862098

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'TEMPORAL'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Feb 2021 17:39:45

US3862098

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered '54'	Carrie Kibler (b) (4)	03 Feb 2021 17:39:45
	(b) (4)	

US3862098

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User entered 'bpm'	System	03 Feb 2021 17:39:45

US3862098

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered '16'	Carrie Kibler (b) (4)	03 Feb 2021 17:39:45
	(b) (4)	

US3862098

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User entered 'breaths/min'	System	03 Feb 2021 17:39:45

US3862098

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '130'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Feb 2021 17:39:45

US3862098

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User entered 'mmHg'	System	03 Feb 2021 17:39:45

US3862098

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '84'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Feb 2021 17:39:45

US3862098

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User entered 'mmHg'	System	03 Feb 2021 17:39:45

US3862098

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:32:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Feb 2021 16:52:04

US3862098

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:32:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered '03 Feb 2021'	Carrie Kibler (b) (4)	03 Feb 2021 16:52:04
	(b) (4)	

US3862098

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Yes (Y)'	(b) (4)	
	Carrie Kibler (b) (4)	03 Feb 2021 17:13:41
	(b) (4)	

US3862098

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	03 Feb 2021 17:13:41
	(b) (4)	

US3862098

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	03 Feb 2021 17:13:41
	(b) (4)	

US3862098

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User entered 'mRNA-1273'	System	03 Feb 2021 17:13:41
DataPoint set to visible.	System	13 Jan 2021 22:15:55

US3862098

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '03 Feb 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Feb 2021 17:13:41

US3862098

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered '11:07'	Carrie Kibler (b) (4)	03 Feb 2021 17:13:41
	(b) (4)	

US3862098

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User entered '03 Feb 2021 11:07'	System	03 Feb 2021 17:13:41

US3862098

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Left Arm (LEFT ARM)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Feb 2021 17:13:41

US3862098

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User entered 'ONCE'	System	03 Feb 2021 17:13:41

US3862098

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:46

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User entered 'INTRAMUSCULAR'	System	03 Feb 2021 17:13:41

US3862098

Folder: OL-D29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Feb 2021 16:53:02

US3862098

Folder: OL-D29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User entered 'I'	System	03 Feb 2021 16:53:02

US3862098

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	10 Feb 2021 15:07:31
	(b) (4)	

US3862098

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered '10 Feb 2021'	Thea Marie Cordero	10 Feb 2021 15:07:31
	(b) (4)	

US3862098

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Thea Marie Cordero	10 Feb 2021 15:07:31
	(b) (4)	

US3862098

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered empty.	Thea Marie Cordero	10 Feb 2021 15:07:31
	(b) (4)	

US3862098

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	10 Feb 2021 15:07:37
	(b) (4)	

US3862098

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:45
User entered 'I'	System	10 Feb 2021 15:07:37

US3862098

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Mar 2021 18:16:03
	(b) (4)	

US3862098

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:46

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered '17 Mar 2021'	Carrie Kibler (b) (4)	17 Mar 2021 18:16:03
	(b) (4)	

US3862098

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Clinic (Clinic)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	17 Mar 2021 18:16:03

US3862098

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User entered 'OLD57'	System	17 Mar 2021 18:16:03

US3862098

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Yes (Y)'	(b) (4)	
	Chanei Henry (b) (4)	25 Mar 2021 21:01:07
	(b) (4)	

US3862098

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '17 Mar 2021'	(b) (4)	
	Chanei Henry (b) (4)	25 Mar 2021 21:01:07
	(b) (4)	

US3862098

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered '11:39'	Chanei Henry (b) (4)	25 Mar 2021 21:01:07
	(b) (4)	

US3862098

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User entered '17 Mar 2021 11:39'	System	25 Mar 2021 21:01:07

US3862098

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered '98.4' F	Chanei Henry (b) (4)	25 Mar 2021 21:01:07
	(b) (4)	

US3862098

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered 'Other (Other)'	Chanei Henry (b) (4)	25 Mar 2021 21:01:07
	(b) (4)	

US3862098

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered 'Temporal'	Chanei Henry (b) (4)	25 Mar 2021 21:01:07
	(b) (4)	

US3862098

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '51'	(b) (4) Chanei Henry (b) (4)	25 Mar 2021 21:01:07
	(b) (4)	

US3862098

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User entered 'bpm'	System	25 Mar 2021 21:01:07

US3862098

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '16'	(b) (4)	
	Chanei Henry (b) (4)	25 Mar 2021 21:01:07
	(b) (4)	

US3862098

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User entered 'breaths/min'	System	25 Mar 2021 21:01:07

US3862098

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '116'	(b) (4)	
	Chanei Henry (b) (4)	25 Mar 2021 21:01:07
	(b) (4)	

US3862098

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User entered 'mmHg'	System	25 Mar 2021 21:01:07

US3862098

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '66'	(b) (4)	
	Chanei Henry (b) (4)	25 Mar 2021 21:01:07
	(b) (4)	

US3862098

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User entered 'mmHg'	System	25 Mar 2021 21:01:07

US3862098

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18

US3862098

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:46

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18

US3862098

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:32:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered 'Yes (Y)'	(b) (4)	17 Mar 2021 18:16:10
	Carrie Kibler (b) (4)	
	(b) (4)	

US3862098

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:32:46

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered '17 Mar 2021'	Carrie Kibler (b) (4)	17 Mar 2021 18:16:10
	(b) (4)	

US3862098

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Mar 2021 18:16:18
	(b) (4)	

US3862098

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '17 Mar 2021'	(b) (4)	
	Carrie Kibler (b) (4)	17 Mar 2021 18:16:18
	(b) (4)	

US3862098

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User entered '11:46'	(b) (4) Carrie Kibler (b) (4) (b) (4)	17 Mar 2021 18:16:18

US3862098

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:43:18
User entered '17 Mar 2021 11:46'	System	17 Mar 2021 18:16:18

US3862098

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:32:46

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:33:01
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:15:39
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	05 Oct 2020 21:54:20

US3862098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:46

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:20
	(b) (4)	
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	06 Jan 2021 21:47:56
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Jan 2021 21:47:56
	(b) (4)	
Data point term sent to Coder	System	06 Jan 2021 21:47:04
DataPoint Un-verified.	Carrie Kibler (b) (4)	06 Jan 2021 21:46:56
	(b) (4)	
Coding entries removed.	Carrie Kibler (b) (4)	06 Jan 2021 21:46:56
	(b) (4)	
User entered 'hypertension' reason for change: Data Entry Error	Carrie Kibler (b) (4)	06 Jan 2021 21:46:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:25:16
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 08:06:32
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 08:06:32
	(b) (4)	
Data point term sent to Coder	System	05 Oct 2020 21:56:39
User entered 'new HTN diagnosis'	Sandra Francisco (b) (4)	05 Oct 2020 21:55:48
	(b) (4)	

US3862098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:25:18
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	05 Oct 2020 21:55:48

US3862098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:25:20
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	05 Oct 2020 21:55:48

US3862098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:25:22
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	05 Oct 2020 21:55:48

US3862098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:46

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:25:24
User entered '29 Sep 2020'	Sandra Francisco (b) (4) (b) (4)	05 Oct 2020 21:55:48

US3862098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:46

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:20
DataPoint Verified.	(b) (4)	23 Nov 2020 16:25:47
	(b) (4), (b) (6)	
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	05 Oct 2020 21:56:37
User entered empty; reason for change Per Query Resolution	Sandra Francisco (b) (4)	05 Oct 2020 21:56:37
	(b) (4)	
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	05 Oct 2020 21:55:48
User entered '12:32'	Sandra Francisco (b) (4)	05 Oct 2020 21:55:48
	(b) (4)	

US3862098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 21:56:37
User entered '29 Sep 2020 12:32'	System	05 Oct 2020 21:55:48

US3862098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:20
	(b) (4)	
DataPoint Un-verified.	Carrie Kibler (b) (4)	06 Jan 2021 21:46:56
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Carrie Kibler (b) (4)	06 Jan 2021 21:46:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:25:49
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	05 Oct 2020 21:55:48
	(b) (4)	

US3862098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:20
	(b) (4)	
DataPoint Un-verified.	Carrie Kibler (b) (4)	06 Jan 2021 21:46:56
	(b) (4)	
User entered '15 Oct 2020' reason for change: New Information	Carrie Kibler (b) (4)	06 Jan 2021 21:46:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:25:52
User entered empty.	Sandra Francisco (b) (4)	05 Oct 2020 21:55:48
	(b) (4)	

US3862098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:46

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

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:25:56
User entered empty.	Sandra Francisco (b) (4) (b) (4)	05 Oct 2020 21:55:48

US3862098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 21:55:48

US3862098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:46

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:20
User closed query 'In source, the severity/grade is blank on AE form. Please update the source with a late entry.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:12:26
Query 'In source, the severity/grade is blank on AE form. Please update the source with a late entry.' answered with 'updated: EDC and source match' (Site from CRA).	Sandra Francisco (b) (4) (b) (4)	24 Nov 2020 19:01:39
User opened query 'In source, the severity/grade is blank on AE form. Please update the source with a late entry.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 17:00:21
User entered 'Grade 3/Severe (Grade 3/Severe)'	Sandra Francisco (b) (4) (b) (4)	05 Oct 2020 21:55:48

US3862098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:25:59
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	05 Oct 2020 21:55:48

US3862098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:26:17
User entered '0'	Sandra Francisco (b) (4) (b) (4)	05 Oct 2020 21:55:48

US3862098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:26:19
User entered '0'	Sandra Francisco (b) (4) (b) (4)	05 Oct 2020 21:55:48

US3862098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:26:21
User entered '0'	Sandra Francisco (b) (4) (b) (4)	05 Oct 2020 21:55:48

US3862098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:46

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:26:24
User entered empty.	Sandra Francisco (b) (4) (b) (4)	05 Oct 2020 21:55:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:46

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:26:25
User entered empty.	Sandra Francisco (b) (4) (b) (4)	05 Oct 2020 21:55:48

US3862098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:26:28
User entered empty.	Sandra Francisco (b) (4) (b) (4)	05 Oct 2020 21:55:48

US3862098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:26:30
User entered empty.	Sandra Francisco (b) (4) (b) (4)	05 Oct 2020 21:55:48

US3862098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:26:31
User entered '0'	Sandra Francisco (b) (4) (b) (4)	05 Oct 2020 21:55:48

US3862098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:26:39
User entered '0'	Sandra Francisco (b) (4) (b) (4)	05 Oct 2020 21:55:48

US3862098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:26:41
User entered '0'	Sandra Francisco (b) (4) (b) (4)	05 Oct 2020 21:55:48

US3862098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:26:43
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Oct 2020 21:56:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Oct 2020 21:56:10
User entered 'Not Related (NOT RELATED)' reason for change: New Information	Sandra Francisco (b) (4) (b) (4)	05 Oct 2020 21:56:10
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Oct 2020 21:55:48
User entered empty.	Sandra Francisco (b) (4) (b) (4)	05 Oct 2020 21:55:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:26:46
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Oct 2020 21:56:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Oct 2020 21:56:10
User entered 'Not Related (NOT RELATED)' reason for change: New Information	Sandra Francisco (b) (4) (b) (4)	05 Oct 2020 21:56:10
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Oct 2020 21:55:48
User entered empty.	Sandra Francisco (b) (4) (b) (4)	05 Oct 2020 21:55:48

US3862098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:46

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:38:18
User closed query 'Per CDM: "Action taken with investigational product" is recorded as "Investigational Product Withdrawn"; however, "Dose discontinuation" form is not filled in. Please review and update all related eCRF forms. Thank you.' (Site from DM).		20 Nov 2020 13:46:58
Query 'Per CDM: "Action taken with investigational product" is recorded as "Investigational Product Withdrawn"; however, "Dose discontinuation" form is not filled in. Please review and update all related eCRF forms. Thank you.' answered with 'Updated' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	18 Nov 2020 20:32:40
User opened query 'Per CDM: "Action taken with investigational product" is recorded as "Investigational Product Withdrawn"; however, "Dose discontinuation" form is not filled in. Please review and update all related eCRF forms. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 13:27:00
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Oct 2020 21:56:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Oct 2020 21:56:10
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: New Information	Sandra Francisco (b) (4) (b) (4)	05 Oct 2020 21:56:10
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Oct 2020 21:55:48
User entered empty.	Sandra Francisco (b) (4) (b) (4)	05 Oct 2020 21:55:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:46

None

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 16:26:55
User entered '0'	Sandra Francisco (b) (4)	05 Oct 2020 21:55:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:20
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM). Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'update: concomitant medication has been updated with appropriate medication. EDC reflects source document ' (Site from DM). User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM). User entered 'I'	(b) (4) (b) (4), (b) (6) Sandra Francisco (b) (4) (b) (4) (b) (4), (b) (6) Sandra Francisco (b) (4) (b) (4)	25 Nov 2020 14:16:48 24 Nov 2020 19:14:06 07 Nov 2020 10:28:53 05 Oct 2020 21:55:48

US3862098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:27:03
User entered '0'	Sandra Francisco (b) (4) (b) (4)	05 Oct 2020 21:55:48

US3862098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:46

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:20
	(b) (4)	
DataPoint Un-verified.	Carrie Kibler (b) (4)	06 Jan 2021 21:46:56
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Carrie Kibler (b) (4)	06 Jan 2021 21:46:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:27:04
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Oct 2020 21:56:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Oct 2020 21:56:10
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: New Information	Sandra Francisco (b) (4)	05 Oct 2020 21:56:10
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Oct 2020 21:55:48
User entered empty.	Sandra Francisco (b) (4)	05 Oct 2020 21:55:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:46

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:27:06
User entered empty.	Sandra Francisco (b) (4) (b) (4)	05 Oct 2020 21:55:48

US3862098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:46

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:27:08
User entered empty.	Sandra Francisco (b) (4) (b) (4)	05 Oct 2020 21:55:48

US3862098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:46

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Oct 2020 21:55:48

US3862098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:46

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 21:55:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:32:46

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:33:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:18:37
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:21:02

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 16:24:50
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 22:22:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 22:22:37
	(b) (4)	
Data point term sent to Coder	System	31 Aug 2020 22:21:49
User entered 'metoprolol'	Carrie Kibler (b) (4)	31 Aug 2020 22:21:31
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:21:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered 'svt'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:21:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered '25'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:21:31

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered 'mg (mg)'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:21:31

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered empty.	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:21:31

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered 'twice daily (BID)'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:21:31

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered empty.	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:21:31

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered 'Oral (ORAL)'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:21:31

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered empty.	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:21:31

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered 'un UNK 2015'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:21:31

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered '0'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:21:31

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:21:31

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered empty.	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:21:31

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:21:31

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	31 Aug 2020 22:21:31

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 22:21:31

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 22:21:31

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 22:23:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 22:23:39
Data point term sent to Coder	System	31 Aug 2020 22:22:49
User entered 'multivitamin'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:22:14

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:22:14

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered 'supplement'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:22:14

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered 'I'	Carrie Kibler (b) (4)	31 Aug 2020 22:22:14
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered 'tablet (TABLET)'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:22:14

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered empty.	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:22:14

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 22:22:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 22:22:23
User entered 'once daily (QD)' reason for change: Data Entry Error	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:22:23
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 22:22:14
User entered empty.	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:22:14

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered empty.	Carrie Kibler (b) (4)	31 Aug 2020 22:22:14
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered 'Oral (ORAL)'	Carrie Kibler (b) (4)	31 Aug 2020 22:22:14
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered empty.	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:22:14

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered 'un UNK 2018'	Carrie Kibler (b) (4)	31 Aug 2020 22:22:14
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered '0'	Carrie Kibler (b) (4)	31 Aug 2020 22:22:14
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:22:14

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered empty.	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:22:14

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:22:14

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 22:22:23
User entered empty.	System	31 Aug 2020 22:22:14

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 22:22:23
User entered empty.	System	31 Aug 2020 22:22:14

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 22:22:23
User entered empty.	System	31 Aug 2020 22:22:14

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 22:25:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 22:25:08
Data point term sent to Coder	System	31 Aug 2020 22:23:50
User entered 'fish oil'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:22:53

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:22:53

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered 'supplement'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:22:53

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered 'I'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:22:53

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered 'tablet (TABLET)'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:22:53

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered empty.	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:22:53

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered 'once daily (QD)'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:22:53

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered empty.	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:22:53

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered 'Oral (ORAL)'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:22:53

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered empty.	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:22:53

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:46

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered 'un UNK 2015'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:22:53

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered '0'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:22:53

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:22:53

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered empty.	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:22:53

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:22:53

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 22:22:53

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 22:22:53

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 22:22:53

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 20:20:57
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 20:20:57
	(b) (4)	
Data point term sent to Coder	System	23 Nov 2020 20:20:09
Coding entries removed.	Trent Davis (b) (4)	23 Nov 2020 20:19:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:24:50
	(b) (4), (b) (6)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 22:24:41
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 22:24:41
	(b) (4)	
Data point term sent to Coder	System	31 Aug 2020 22:23:50
User entered 'melatonin'	Carrie Kibler (b) (4)	31 Aug 2020 22:23:34
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
DataPoint Un-verified.	Trent Davis (b) (4)	23 Nov 2020 20:19:47
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Trent Davis (b) (4)	23 Nov 2020 20:19:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered 'No (N)'	Carrie Kibler (b) (4)	31 Aug 2020 22:23:34
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User closed query 'Per DM CLR : Please note that Con Med indication should reflect a medical condition instead of what the drug does. Please review and update the Con Med indication with the corresponding AE or Med History eCRF so there is an appropriate match. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:20:35
Query 'Per DM CLR : Please note that Con Med indication should reflect a medical condition instead of what the drug does. Please review and update the Con Med indication with the corresponding AE or Med History eCRF so there is an appropriate match. ' answered with 'data corrected' (Site from DM).	Trent Davis (b) (4) (b) (4)	23 Nov 2020 20:20:20
DataPoint Un-verified.	Trent Davis (b) (4) (b) (4)	23 Nov 2020 20:19:47
User entered 'Prophylaxis for insomnia' reason for change: Data Entry Error	Trent Davis (b) (4) (b) (4)	23 Nov 2020 20:19:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:24:50
User opened query 'Per DM CLR : Please note that Con Med indication should reflect a medical condition instead of what the drug does. Please review and update the Con Med indication with the corresponding AE or Med History eCRF so there is an appropriate match. ' (Site from DM).		05 Oct 2020 19:24:45
User entered 'sleep aid'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:23:34

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User closed query 'Per DM CLR : Please note that numeric doses, if known, are preferred over "1 tablet." Please provide the actual dose for this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:20:36
Query 'Per DM CLR : Please note that numeric doses, if known, are preferred over "1 tablet." Please provide the actual dose for this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'data entered' (Site from DM).	Trent Davis (b) (4) (b) (4)	23 Nov 2020 20:20:37
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:24:50
User opened query 'Per DM CLR : Please note that numeric doses, if known, are preferred over "1 tablet." Please provide the actual dose for this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).		05 Oct 2020 19:25:02
User entered '1'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:23:34

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered 'tablet (TABLET)'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:23:34

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered empty.	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:23:34

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered 'as needed (PRN)'	Carrie Kibler (b) (4)	31 Aug 2020 22:23:34
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered empty.	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:23:34

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered 'Oral (ORAL)'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:23:34

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered empty.	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:23:34

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:46

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered 'un Feb 2020'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:23:34

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered '0'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:23:34

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:23:34

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered empty.	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:23:34

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:24:50
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:23:34

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 22:23:34

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 22:23:34

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 22:23:34

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 19:15:00
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	24 Nov 2020 19:15:00
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	24 Nov 2020 19:13:43
User entered 'losartan'	Sandra Francisco (b) (4)	24 Nov 2020 19:13:02
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered 'No (N)'	Sandra Francisco (b) (4)	24 Nov 2020 19:13:02
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered 'hypertension'	Sandra Francisco (b) (4)	24 Nov 2020 19:13:02
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered '25'	Sandra Francisco (b) (4)	24 Nov 2020 19:13:02
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered 'mg (mg)'	Sandra Francisco (b) (4)	24 Nov 2020 19:13:02
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	24 Nov 2020 19:13:02
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered 'once daily (QD)'	Sandra Francisco (b) (4)	24 Nov 2020 19:13:02
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	24 Nov 2020 19:13:02
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered 'Oral (ORAL)'	Sandra Francisco (b) (4)	24 Nov 2020 19:13:02
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	24 Nov 2020 19:13:02
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered '01 Oct 2020'	Sandra Francisco (b) (4)	24 Nov 2020 19:13:02
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered '0'	Sandra Francisco (b) (4)	24 Nov 2020 19:13:02
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:01
	(b) (4)	
Signature has been broken.	Sandra Francisco (b) (4)	23 Apr 2021 20:37:06
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Sandra Francisco (b) (4)	23 Apr 2021 20:37:06
	(b) (4)	
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	24 Nov 2020 19:13:02
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:01
	(b) (4)	
Signature has been broken.	Sandra Francisco (b) (4)	23 Apr 2021 20:37:06
	(b) (4)	
User entered '19 Apr 2021' reason for change: New Information	Sandra Francisco (b) (4)	23 Apr 2021 20:37:06
	(b) (4)	
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	24 Nov 2020 19:13:02
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered 'No (N)'	Sandra Francisco (b) (4)	24 Nov 2020 19:13:02
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 19:13:02

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 19:13:02

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Nov 2020 19:13:02

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: UBIDECARENONE, PRODUCTSYNONYM: COQ10 [UBIDECARENONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Jan 2021 22:18:30
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Jan 2021 22:18:30
	(b) (4)	
Data point term sent to Coder	System	06 Jan 2021 21:52:05
User entered 'coq10'	Carrie Kibler (b) (4)	06 Jan 2021 21:51:28
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	06 Jan 2021 21:51:28
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered 'general well-being'	Carrie Kibler (b) (4)	06 Jan 2021 21:51:28
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered '100' reason for change: New Information	Thea Marie Cordero	13 Jan 2021 22:28:16
	(b) (4)	
User entered '1'	Carrie Kibler (b) (4)	06 Jan 2021 21:51:28
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered 'mg (mg)' reason for change: New Information	Thea Marie Cordero	13 Jan 2021 22:28:16
	(b) (4)	
User entered 'tablet (TABLET)'	Carrie Kibler (b) (4)	06 Jan 2021 21:51:28
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	06 Jan 2021 21:51:28
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered 'once daily (QD)'	Carrie Kibler (b) (4)	06 Jan 2021 21:51:28
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	06 Jan 2021 21:51:28
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered 'Oral (ORAL)'	Carrie Kibler (b) (4)	06 Jan 2021 21:51:28
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	06 Jan 2021 21:51:28
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered '23 Dec 2020'	Carrie Kibler (b) (4)	06 Jan 2021 21:51:28
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	06 Jan 2021 21:51:28
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	06 Jan 2021 21:51:28
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	06 Jan 2021 21:51:28
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	06 Jan 2021 21:51:28
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 21:51:28

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 21:51:28

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Jan 2021 21:51:28

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Apr 2021 20:38:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 20:38:55
Data point term sent to Coder	System	23 Apr 2021 20:38:05
User entered 'losartan'	Sandra Francisco (b) (4) (b) (4)	23 Apr 2021 20:37:58

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:01
	(b) (4)	
User entered 'No (N)'	Sandra Francisco (b) (4)	23 Apr 2021 20:37:58
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:01
	(b) (4)	
User entered 'hypertension'	Sandra Francisco (b) (4)	23 Apr 2021 20:37:58
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:01
	(b) (4)	
User entered '12.5'	Sandra Francisco (b) (4)	23 Apr 2021 20:37:58
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:01
	(b) (4)	
User entered 'mg (mg)'	Sandra Francisco (b) (4)	23 Apr 2021 20:37:58
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:01
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	23 Apr 2021 20:37:58
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:01
	(b) (4)	
User entered 'once daily (QD)'	Sandra Francisco (b) (4)	23 Apr 2021 20:37:58
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:01
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	23 Apr 2021 20:37:58
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:01
	(b) (4)	
User entered 'Oral (ORAL)'	Sandra Francisco (b) (4)	23 Apr 2021 20:37:58
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:01
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	23 Apr 2021 20:37:58
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:01
	(b) (4)	
User entered '19 Apr 2021'	Sandra Francisco (b) (4)	23 Apr 2021 20:37:58
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:01
	(b) (4)	
User entered '0'	Sandra Francisco (b) (4)	23 Apr 2021 20:37:58
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:01
	(b) (4)	
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	23 Apr 2021 20:37:58
	(b) (4)	

US3862098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:01
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	23 Apr 2021 20:37:58
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:01
	(b) (4)	
User entered 'No (N)'	Sandra Francisco (b) (4)	23 Apr 2021 20:37:58
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 20:37:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 20:37:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 20:37:58

US3862098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 12 Aug 2021 13:32:46

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
	(b) (4)	
User entered 'No (N)'	Chanei Henry (b) (4)	25 Mar 2021 20:51:44
	(b) (4)	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:32:46

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:32:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User closed query 'Per CDM re-query: I apologize for the previous query. Please be aware that "Date of dosing discontinuation" should not be the date what was asked. Please consider updating the date when subject withdrew dosing and according to a AE#1 this date is 29Sep2020. Please review and update or clarify otherwise. Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Dec 2020 08:43:21
Query 'Per CDM re-query: I apologize for the previous query. Please be aware that "Date of dosing discontinuation" should not be the date what was asked. Please consider updating the date when subject withdrew dosing and according to a AE#1 this date is 29Sep2020. Please review and update or clarify otherwise. Thank you!' answered with 'data corrected new HTN diagnosis came on 29SEP2020 which is the date of dosing discontinuation. ' (Site from DM).	Trent Davis (b) (4) (b) (4)	11 Dec 2020 19:40:13
User entered '29 Sep 2020' reason for change: Data Entry Error	Trent Davis (b) (4) (b) (4)	11 Dec 2020 19:38:33
User opened query 'Per CDM re-query: I apologize for the previous query. Please be aware that "Date of dosing discontinuation" should not be the date what was asked. Please consider updating the date when subject withdrew dosing and according to a AE#1 this date is 29Sep2020. Please review and update or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 10:25:35
User closed query 'Per CDM: Per CCGs pgs 41-42, dosing discontinuation should be indicated as the last date of exposure which was on Visit 1 Day 1 on 31Aug2020. Please confirm and update where necessary. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 10:25:35
Query 'Per CDM: Per CCGs pgs 41-42, dosing discontinuation should be indicated as the last date of exposure which was on Visit 1 Day 1 on 31Aug2020. Please confirm and update where necessary. Thank you.' answered with 'Updated' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	30 Nov 2020 18:37:30
DataPoint Un-verified.	Shetel Anassi (b) (4) (b) (4)	30 Nov 2020 18:37:24

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EAB) (1725)

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:32:46

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '31 Aug 2020' reason for change: Data Entry Error	Shetel Anassi (b) (4)	30 Nov 2020 18:37:24
User opened query 'Per CDM: Per CCGs pgs 41-42, dosing discontinuation should be indicated as the last date of exposure which was on Visit 1 Day 1 on 31Aug2020. Please confirm and update where necessary. Thank you.' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Nov 2020 14:52:14
	(b) (4), (b) (6)	23 Nov 2020 16:38:55
User entered '29 Sep 2020'	Shetel Anassi (b) (4) (b) (4)	18 Nov 2020 20:33:42

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:32:46

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:32:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:38:57
User entered 'AE (specify) (ADVERSE EVENT)'	Shetel Anassi (b) (4) (b) (4)	18 Nov 2020 20:33:42

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:32:46

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:32:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:30
User closed query 'Per CDM: Per page 44 of CCGs v2.0, record the exact AE log line and do NOT record any AE term text. Please review and reconcile. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 14:20:52
Query 'Per CDM: Per page 44 of CCGs v2.0, record the exact AE log line and do NOT record any AE term text. Please review and reconcile. Thank you.' answered with 'Updated' (Site from DM).	Shetel Anassi (b) (4)	23 Nov 2020 19:23:11
User entered 'AE #1' reason for change: Data Entry Error	(b) (4)	23 Nov 2020 19:23:03
User opened query 'Per CDM: Per page 44 of CCGs v2.0, record the exact AE log line and do NOT record any AE term text. Please review and reconcile. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 13:46:43
User entered 'AE #1: MEDICALLY ATTENDED NEWLY DIAGNOSED HTN. PI AND MEDICAL MONITOR DETERMINED SUBJECT IS NO LONGER ELIGIBLE FOR DOSE 2 BUT SHOULD CONTINUE IN STUDY FOR SAFETY AND EFFICACY ASSESSMENTS.'	Shetel Anassi (b) (4)	18 Nov 2020 20:33:42