

US3862044 (Prod: Baylor College of Medicine)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:38:20

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US3862044

Form: Participant Creation

Data signed: (b) (4) 12 Mar 2021 22:54:16

Generated On: 12 Aug 2021 13:38:20

[Participant ID](#)

US3862044

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

US3862044

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 22:54:26

Generated On: 12 Aug 2021 13:38:20

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Mar 2021 22:54:24

Generated On: 12 Aug 2021 13:38:20

Date of Birth (MMM yyyy)	(b) (6) 1968
Age	52
Age Units	YEARS
Age (Derived)	52
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☒ Not Hispanic or Latino ☐ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3862044

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Mar 2021 22:54:24

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Mar 2021 22:54:24

Generated On: 12 Aug 2021 13:38:20

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Mar 2021 22:54:24

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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) 12 Mar 2021 22:54:24

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Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Mar 2021 22:54:26

Generated On: 12 Aug 2021 13:38:20

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	08:45 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 08:45
Height (xxx.x)	69 in
Weight (xxx.x)	179.6 lb
BMI (xxx.x)	26.57774 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	97.9 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	060 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 22:54:24

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 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) 12 Mar 2021 22:54:24

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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) 12 Mar 2021 22:54:24

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 22:54:26

Generated On: 12 Aug 2021 13:38:20

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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Mar 2021 22:54:26

Generated On: 12 Aug 2021 13:38:20

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

What was the participant's randomization number? 106937

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) 12 Mar 2021 22:54:26

Generated On: 12 Aug 2021 13:38:20

Height	69 in
Weight	179.6 lb

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Mar 2021 22:54:26

Generated On: 12 Aug 2021 13:38:20

Height	69 in
Weight	179.6 lb
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	08:45 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 08:45
Temperature (xxx.x)	97.9 F
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Mar 2021 22:54:26

Generated On: 12 Aug 2021 13:38:20

Height	69 in
Weight	179.6 lb
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	10:54 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 10:54
Temperature (xxx.x)	97.6 F
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 22:54:26

Generated On: 12 Aug 2021 13:38:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 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) 12 Mar 2021 22:54:26

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Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 21 AUG 2020

What was the treatment time? (00:00-23:59) 10:21 (24 HR)

Treatment Date and Time (derived) 21 AUG 2020 10:21

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) 12 Mar 2021 22:54:26

Generated On: 12 Aug 2021 13:38:20

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 AUG 2020

Collection time (00:00-23:59)

09:27 (24 HR)

Collection date and time (derived)

21 AUG 2020 09:27

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Mar 2021 22:54:26

Generated On: 12 Aug 2021 13:38:20

Collection date (dd MMM yyyy)			21 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:11	21 AUG 2020 09:11
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 22:54:26

Generated On: 12 Aug 2021 13:38:20

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 13:38:20

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

21 AUG 2020 10:57

PC Open Date & Time

21 AUG 2020 10:41

PC Close Date & Time

21 AUG 2020 13:11

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.5 °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	22 AUG 2020 09:39
PC Open Date & Time	21 AUG 2020 14:06
PC Close Date & Time	22 AUG 2020 11:59

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:38:20

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

22 AUG 2020 12:07

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

23 AUG 2020 20:39

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

24 AUG 2020 12:00

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:38:20

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

97.5 °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

25 AUG 2020 12:00

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

26 AUG 2020 12:17

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 12:03

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

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

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

21 AUG 2020 10:58

PC Open Date & Time

21 AUG 2020 10:41

PC Close Date & Time

21 AUG 2020 13:11

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:38:20

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

22 AUG 2020 09:39

PC Open Date & Time

21 AUG 2020 14:06

PC Close Date & Time

22 AUG 2020 11:59

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 12:08

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 20:40

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT	DAY 4
Please record - PAIN AT INJECTION SITE.	None ☒
Please select one response below	
Does not interfere with activity	☐
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	☐
Any use of prescription pain reliever or prevents daily activity	☐
Is there any REDNESS AT INJECTION SITE?	Yes ☐
	No ☒
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes ☐
	No ☒
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None ☒
Please select one response below	
Does not interfere with activity	☐
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	☐
Any use of prescription pain reliever or prevents daily activity	☐
PC Time Stamp	24 AUG 2020 12:01
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 12:00

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 12:17

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT	DAY 7
Please record - PAIN AT INJECTION SITE.	None ☒
Please select one response below	
Does not interfere with activity	☐
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	☐
Any use of prescription pain reliever or prevents daily activity	☐
Is there any REDNESS AT INJECTION SITE?	Yes ☐
	No ☒
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes ☐
	No ☒
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None ☒
Please select one response below	
Does not interfere with activity	☐
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	☐
Any use of prescription pain reliever or prevents daily activity	☐
PC Time Stamp	27 AUG 2020 12:03
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:38:20

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 ☐

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:38:20

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 12:56
PC Open Date & Time	21 AUG 2020 10:41
PC Close Date & Time	21 AUG 2020 13:11

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:38:20

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 ☐

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:38:20

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

No ☒

Yes ☐

PC Time stamp	22 AUG 2020 09:39
PC Open Date & Time	21 AUG 2020 14:06
PC Close Date & Time	22 AUG 2020 11:59

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:38:20

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 ☒

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:38:20

Yes ☐	
PC Time stamp	22 AUG 2020 12:08
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:38:20

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:38:20

Yes ☐	
PC Time stamp	23 AUG 2020 20:40
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:38:20

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 ☒

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:38:20

Yes ☐	
PC Time stamp	24 AUG 2020 12:01
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:38:20

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:38:20

Yes ☐	
PC Time stamp	25 AUG 2020 12:01
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:38:20

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:38:20

Yes ☐	
PC Time stamp	26 AUG 2020 12:18
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:38:20

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 ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:38:20

	Yes ☐
PC Time stamp	27 AUG 2020 12:04
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3862044

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 22:54:24

Generated On: 12 Aug 2021 13:38:20

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3862044

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 22:54:19

Generated On: 12 Aug 2021 13:38:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862044

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 22:54:19

Generated On: 12 Aug 2021 13:38:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862044

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 22:54:16

Generated On: 12 Aug 2021 13:38:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862044

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 22:54:19

Generated On: 12 Aug 2021 13:38:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862044

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 22:54:19

Generated On: 12 Aug 2021 13:38:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862044

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 22:54:37

Generated On: 12 Aug 2021 13:38:20

Was this visit performed?	Yes ☒
	No ☐

Visit date (dd MMM yyyy)	18 SEP 2020
--------------------------	-------------

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

Folder OID	VISIT2
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US3862044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Mar 2021 22:54:37

Generated On: 12 Aug 2021 13:38:20

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	18 SEP 2020
Time of assessment (00:00-23:59)	09:06 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 09:06
Temperature (xxx.x)	98.8 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	076 mmHg
Diastolic Blood Pressure units	MMHG

US3862044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Mar 2021 22:54:37

Generated On: 12 Aug 2021 13:38:20

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

US3862044

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 22:54:37

Generated On: 12 Aug 2021 13:38:20

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.

US3862044

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Mar 2021 22:54:37

Generated On: 12 Aug 2021 13:38:20

Was study treatment given? Yes ☐
No ☒

If No, reason not given

Participant declined due to Adverse Event ☒
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3862044

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Mar 2021 22:54:37

Generated On: 12 Aug 2021 13:38:20

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 SEP 2020

Collection time (00:00-23:59)

09:15 (24 HR)

Collection date and time (derived)

18 SEP 2020 09:15

US3862044

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Mar 2021 22:54:37

Generated On: 12 Aug 2021 13:38:20

Collection date (dd MMM yyyy)			18 SEP 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	09:10	18 SEP 2020 09:10

US3862044

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 22:54:37

Generated On: 12 Aug 2021 13:38:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862044

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 22:54:19

Generated On: 12 Aug 2021 13:38:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862044

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 22:54:19

Generated On: 12 Aug 2021 13:38:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862044

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 22:54:19

Generated On: 12 Aug 2021 13:38:20

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3862044

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 22:54:19

Generated On: 12 Aug 2021 13:38:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862044

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 22:54:19

Generated On: 12 Aug 2021 13:38:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862044

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 22:54:19

Generated On: 12 Aug 2021 13:38:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862044

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 22:54:39

Generated On: 12 Aug 2021 13:38:20

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	16 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3862044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Mar 2021 22:54:39

Generated On: 12 Aug 2021 13:38:20

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	16 OCT 2020
Time of assessment (00:00-23:59)	15:55 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 15:55
Temperature (xxx.x)	097.8 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	060 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	079 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3862044

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 22:54:37

Generated On: 12 Aug 2021 13:38:20

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.

US3862044

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Mar 2021 22:54:37

Generated On: 12 Aug 2021 13:38:20

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 OCT 2020

Collection time (00:00-23:59)

16:15 (24 HR)

Collection date and time (derived)

16 OCT 2020 16:15

US3862044

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 22:54:37

Generated On: 12 Aug 2021 13:38:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 OCT 2020 06:04:15

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 OCT 2020 18:55:24

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 NOV 2020 12:00:28

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3862044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 NOV 2020 12:00:55
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3862044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 NOV 2020 00:02:53

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3862044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 DEC 2020 12:01:56
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3862044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

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

13 DEC 2020 05:45:11

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3862044

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:38:20

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

US3862044

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 22:54:24

Generated On: 12 Aug 2021 13:38:20

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3862044

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 22:54:24

Generated On: 12 Aug 2021 13:38:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862044

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 22:54:16

Generated On: 12 Aug 2021 13:38:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862044

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 22:54:16

Generated On: 12 Aug 2021 13:38:20

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3862044

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:38:20

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

US3862044

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 12 Aug 2021 13:38:20

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3862044

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:08:32

Generated On: 12 Aug 2021 13:38:20

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 UNBLND_DECIDE

US3862044

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 14:08:32

Generated On: 12 Aug 2021 13:38:20

Date of updated informed consent (dd MMM yyyy)	
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	True
Was the participant unblinded?	Yes ☒ No ☐
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ☒ Amendment 6 or later ☐
Date of unblinding (dd MMM yyyy)	15 DEC 2020
Participant randomization assignment	mRNA-1273 ☐ Placebo ☒
Actual Dose 1	mRNA-1273 ☐ Placebo ☒ Not Administered ☐
Actual Dose 2	mRNA-1273 ☐ Placebo ☒ Not Administered ☐
Will participant receive mRNA-1273?	Yes ☐ No ☒
Placebo Only Flag	1
Continuing with mRNA-1273	

US3862044

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:38:20

Was the sample collected?	Yes ☐
	No ☐

Collection date (<i>dd MMM yyyy</i>)	_____
Collection time (<i>00:00-23:59</i>)	_____
Collection date and time (derived)	_____

US3862044

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:38:20

Was the sample collected?

Yes ☐

No ☐

Collection date (*dd MMM yyyy*)

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

Collection Date and Time (derived)

US3862044

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 22:54:16

Generated On: 12 Aug 2021 13:38:20

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Mar 2021 14:01:59

Generated On: 12 Aug 2021 13:38:20

AEID

Adverse event

IRREGULAR HEART BEAT

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

10 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

10 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Mar 2021 14:01:59

Generated On: 12 Aug 2021 13:38:20

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☒ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
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)	_____

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Mar 2021 22:54:16

Generated On: 12 Aug 2021 13:38:20

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

Yes ☒

No ☐

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

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Mar 2021 15:01:51

Generated On: 12 Aug 2021 13:38:20

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GERD

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Mar 2021 15:01:51

Generated On: 12 Aug 2021 13:38:20

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Mar 2021 15:01:51

Generated On: 12 Aug 2021 13:38:20

Name of Medication VITAMIN C

Prophylaxis Yes ☒
No ☐

Indication VITAMIN 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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Mar 2021 15:01:51

Generated On: 12 Aug 2021 13:38:20

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Mar 2021 15:01:51

Generated On: 12 Aug 2021 13:38:20

Name of Medication VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication VITAMIN 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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Mar 2021 15:01:51

Generated On: 12 Aug 2021 13:38:20

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Mar 2021 15:01:51

Generated On: 12 Aug 2021 13:38:20

Name of Medication VITAMIN E

Prophylaxis Yes ☒
No ☐

Indication VITAMIN 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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Mar 2021 15:01:51

Generated On: 12 Aug 2021 13:38:20

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Mar 2021 15:01:51

Generated On: 12 Aug 2021 13:38:20

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Mar 2021 15:01:51

Generated On: 12 Aug 2021 13:38:20

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

US3862044

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 29 Mar 2021 14:02:00

Generated On: 12 Aug 2021 13:38:20

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3862044

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 22 Mar 2021 15:01:51

Generated On: 12 Aug 2021 13:38:20

Date of dosing discontinuation (dd MMM yyyy) 18 SEP 2020

Primary reason for dosing discontinuation

AE (specify) ☒

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3862044

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 12 Mar 2021 22:54:16

Generated On: 12 Aug 2021 13:38:20

Date of study discontinuation/completion (dd MMM yyyy) 15 DEC 2020

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 REQUEST TO UNBLIND/EUA COVID-19 VACCINE

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

US3862044 (Prod: Baylor College of Medicine)

US3862044

Form: Participant Creation

Generated On: 12 Aug 2021 13:38:20

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'US3862044'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 14:30:52

US3862044

Form: Participant Creation

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 21:52:31

US3862044

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:38:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:27:41

US3862044

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered '21 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 14:30:53

US3862044

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:38:20

[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 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered 'Clinic (Clinic)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:27:41

US3862044

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:38:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered 'SCRN'	System	21 Aug 2020 15:27:41

US3862044

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:38:20

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered (b) (6) 1968'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 14:30:54

US3862044

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:38:20

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered '52'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:28:06

US3862044

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:38:20

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered 'YEARS'	System	21 Aug 2020 15:28:06

US3862044

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:38:20

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered '52'	System	21 Aug 2020 15:28:26

US3862044

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:38:20

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered 'Male (M)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:28:06

US3862044

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:38:20

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:28:06

US3862044

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:38:20

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered '1'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:28:06

US3862044

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:38:20

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered '0'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:28:06

US3862044

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:38:20

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered '0'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:28:06

US3862044

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:38:20

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered '0'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:28:06

US3862044

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:38:20

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered '0'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:28:06

US3862044

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:38:20

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered '0'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:28:06

US3862044

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:38:20

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered empty.	(b) (4)	21 Aug 2020 15:28:06
	Sandra Francisco (b) (4)	
	(b) (4)	

US3862044

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:38:20

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered '0'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:28:06

US3862044

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:38:20

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered '0'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:28:06

US3862044

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:38:20

Date of Informed Consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered '21 Aug 2020'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:28:26

US3862044

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered 'Aug 2020'	System	21 Aug 2020 15:28:26

US3862044

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered '2020'	System	21 Aug 2020 15:28:26

US3862044

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:38:20

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
	(b) (4)	
User entered 'Amendment 2 (2)'	Sandra Francisco (b) (4)	21 Aug 2020 15:28:26
	(b) (4)	

US3862044

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:28:26

US3862044

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:38:20

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered empty.	(b) (4)	21 Aug 2020 15:28:26
	Sandra Francisco (b) (4)	
	(b) (4)	

US3862044

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:38:20

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered empty.	(b) (4)	21 Aug 2020 15:28:26
	Sandra Francisco (b) (4)	
	(b) (4)	

US3862044

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:38:20

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
	(b) (4)	
User entered 'No (N)'	Sandra Francisco (b) (4)	21 Aug 2020 15:28:26
	(b) (4)	

US3862044

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:38:20

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 14:30:53

US3862044

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:38:20

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered '1'	System	21 Aug 2020 15:28:30

US3862044

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
	(b) (4)	
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	21 Aug 2020 15:28:30
	(b) (4)	

US3862044

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:38:20

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
	(b) (4)	
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	21 Aug 2020 15:36:43
	(b) (4)	

US3862044

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:38:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	21 Aug 2020 15:38:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:38:22
Data point term sent to Coder	System	21 Aug 2020 15:37:45
User entered 'gastroesophageal reflux disease'	Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:37:24

US3862044

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered 'un UNK 2019'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:37:24

US3862044

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:38:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered '0'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:37:24

US3862044

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:38:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:37:24

US3862044

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered empty.	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:37:24

US3862044

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:38:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered '0'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:37:24

US3862044

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered 'Jan 2019'	System	21 Aug 2020 15:37:24

US3862044

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered '2019'	System	21 Aug 2020 15:37:24

US3862044

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered empty.	System	21 Aug 2020 15:37:24

US3862044

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered empty.	System	21 Aug 2020 15:37:24

US3862044

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:35:33

US3862044

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered '21 Aug 2020'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:35:33

US3862044

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
	(b) (4)	
User entered '08:45'	Sandra Francisco (b) (4)	21 Aug 2020 15:35:33
	(b) (4)	

US3862044

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered '21 Aug 2020 08:45'	System	21 Aug 2020 15:35:33

US3862044

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered '69' in	(b) (4)	
	Sandra Francisco (b) (4)	21 Aug 2020 15:35:33
DataPoint set to visible.	(b) (4)	
	System	21 Aug 2020 15:28:30

US3862044

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered '179.6' lb	(b) (4)	
	Sandra Francisco (b) (4)	21 Aug 2020 15:35:33
DataPoint set to visible.	(b) (4)	
	System	21 Aug 2020 15:28:30

US3862044

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
Amendment Manager: User entered '26.57774'	System	17 Sep 2020 00:17:56
User entered '26.6'	System	21 Aug 2020 15:35:33
DataPoint set to visible.	System	21 Aug 2020 15:28:30

US3862044

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered 'kg/m2'	System	21 Aug 2020 15:35:33
DataPoint set to visible.	System	21 Aug 2020 15:28:30

US3862044

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
	(b) (4)	
User entered '97.9' F	Sandra Francisco (b) (4)	21 Aug 2020 15:35:33
	(b) (4)	

US3862044

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered 'Other (Other)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:35:33

US3862044

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered 'Temporal'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:35:33

US3862044

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered '64'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:35:33

US3862044

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered 'bpm'	System	21 Aug 2020 15:35:33

US3862044

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered '16'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:35:33

US3862044

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered 'breaths/min'	System	21 Aug 2020 15:35:33

US3862044

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered '124'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:35:33

US3862044

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered 'mmHg'	System	21 Aug 2020 15:35:33

US3862044

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered '060'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:35:33

US3862044

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered 'mmHg'	System	21 Aug 2020 15:35:33

US3862044

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37

US3862044

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37

US3862044

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:38:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:31:25

US3862044

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:38:20

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
	(b) (4)	
User entered '21 Aug 2020'	Sandra Francisco (b) (4)	21 Aug 2020 15:31:25
	(b) (4)	

US3862044

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:32:49

US3862044

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
	(b) (4)	
User entered 'No (N)'	Sandra Francisco (b) (4)	21 Aug 2020 15:32:49
	(b) (4)	

US3862044

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:20

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)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered 'No (N)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:32:49

US3862044

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:20

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)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered 'No (N)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:32:49

US3862044

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
	(b) (4)	
User entered 'No (N)'	Sandra Francisco (b) (4)	21 Aug 2020 15:32:49
	(b) (4)	

US3862044

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:20

[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)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered 'No (N)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:32:49

US3862044

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:20

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)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered 'No (N)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:32:49

US3862044

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:20

[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)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered 'No (N)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:32:49

US3862044

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:20

[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)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
	(b) (4)	
User entered 'No (N)'	Sandra Francisco (b) (4)	21 Aug 2020 15:32:49
	(b) (4)	

US3862044

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:20

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)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered 'No (N)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:32:49

US3862044

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:20

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)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered 'No (N)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:32:49

US3862044

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:20

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
	(b) (4)	
User entered 'No (N)'	Sandra Francisco (b) (4)	21 Aug 2020 15:32:49
	(b) (4)	

US3862044

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:20

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered empty.	(b) (4)	21 Aug 2020 15:32:49
	Sandra Francisco (b) (4)	
	(b) (4)	

US3862044

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:20

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered '0'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:32:49

US3862044

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered '0'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:32:49

US3862044

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:20

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)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered '0'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:32:49

US3862044

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:20

[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)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered '0'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:32:49

US3862044

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:20

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)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered '0'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:32:49

US3862044

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered '1'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:32:49

US3862044

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:20

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered '0'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:32:49

US3862044

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:20

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered empty.	(b) (4)	
	Sandra Francisco (b) (4)	21 Aug 2020 15:32:49
	(b) (4)	

US3862044

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:38:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:28:42

US3862044

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered '21 Aug 2020'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:28:42

US3862044

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:38:20

[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 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered 'Clinic (Clinic)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:28:42

US3862044

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:38:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered 'VISIT1'	System	21 Aug 2020 15:28:42

US3862044

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered '21 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 14:50:01

US3862044

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered '106937'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 14:50:01

US3862044

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered '>=18 and <65 years and not at risk (1)'	(b) (4)	
	RWS_ENDPOINT	21 Aug 2020 14:50:01
	ENDPOINT (b) (4)	

US3862044

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:38:20

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)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered 'No (N)'	(b) (4) Chanei Henry (b) (4) (b) (4)	21 Aug 2020 17:07:04

US3862044

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:38:20

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)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered 'No (N)'	(b) (4) Chanei Henry (b) (4) (b) (4)	21 Aug 2020 17:07:04

US3862044

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered 'No (N)'	(b) (4) Chanei Henry (b) (4) (b) (4)	21 Aug 2020 17:07:04

US3862044

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered 'No (N)'	(b) (4) Chanei Henry (b) (4) (b) (4)	21 Aug 2020 17:07:04

US3862044

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:38:20

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered 'No (N)'	(b) (4) Chanei Henry (b) (4) (b) (4)	21 Aug 2020 17:07:04

US3862044

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4)	22 Sep 2020 17:47:08
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 10:38:03
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:57:37

US3862044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:38:20

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
	(b) (4)	
User entered '69' in	Sandra Francisco (b) (4)	21 Aug 2020 15:30:34
	(b) (4)	

US3862044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:38:20

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
	(b) (4)	
User entered '179.6' lb	Sandra Francisco (b) (4)	21 Aug 2020 15:30:34
	(b) (4)	

US3862044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:38:20

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
	(b) (4)	
User entered '69' in	Sandra Francisco (b) (4)	21 Aug 2020 15:30:34
	(b) (4)	

US3862044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:38:20

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered '179.6' lb	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:30:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User accepted default value 'Pre-Dose (PREDOSE)'	Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:30:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Aug 2020 15:31:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 15:31:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Sandra Francisco (b) (4)	21 Aug 2020 15:31:07
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Aug 2020 15:30:34
User entered empty.	System	21 Aug 2020 15:30:34
	Sandra Francisco (b) (4)	21 Aug 2020 15:30:34
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
	(b) (4)	
User entered '21 Aug 2020' reason for change: Data Entry Error	Sandra Francisco (b) (4)	21 Aug 2020 15:31:07
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	21 Aug 2020 15:30:34
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
	(b) (4)	
User entered '08:45' reason for change: Data Entry Error	Sandra Francisco (b) (4)	21 Aug 2020 15:31:07
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	21 Aug 2020 15:30:34
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered '21 Aug 2020 08:45'	System	21 Aug 2020 15:31:07
User entered empty.	System	21 Aug 2020 15:30:34

US3862044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 15:31:16
User entered '97.9' F reason for change: Data Entry Error	System	21 Aug 2020 15:31:16
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Sandra Francisco (b) (4)	21 Aug 2020 15:31:16
User entered '97.9' (non-conformant).	(b) (4)	21 Aug 2020 15:31:07
User entered empty.	System	21 Aug 2020 15:31:07
	Sandra Francisco (b) (4)	21 Aug 2020 15:31:07
	(b) (4)	21 Aug 2020 15:31:07
	Sandra Francisco (b) (4)	21 Aug 2020 15:30:34
	(b) (4)	21 Aug 2020 15:30:34

US3862044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
	(b) (4)	
User entered 'Other (Other)' reason for change: Data Entry Error	Sandra Francisco (b) (4)	21 Aug 2020 15:31:07
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	21 Aug 2020 15:30:34
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
	(b) (4)	
User entered 'Temporal' reason for change: Data Entry Error	Sandra Francisco (b) (4)	21 Aug 2020 15:31:07
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	21 Aug 2020 15:30:34
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
	(b) (4)	
User entered '64' reason for change: Data Entry Error	Sandra Francisco (b) (4)	21 Aug 2020 15:31:07
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	21 Aug 2020 15:30:34
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered 'bpm'	System	21 Aug 2020 15:31:07
User entered empty.	System	21 Aug 2020 15:30:34

US3862044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered '16' reason for change: Data Entry Error	(b) (4)	
	Sandra Francisco (b) (4)	21 Aug 2020 15:31:07
User entered empty.	(b) (4)	
	Sandra Francisco (b) (4)	21 Aug 2020 15:30:34
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered 'breaths/min'	System	21 Aug 2020 15:31:07
User entered empty.	System	21 Aug 2020 15:30:34

US3862044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered '124' reason for change: Data Entry Error	(b) (4)	
	Sandra Francisco (b) (4)	21 Aug 2020 15:31:07
User entered empty.	(b) (4)	
	Sandra Francisco (b) (4)	21 Aug 2020 15:30:34
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered 'mmHg'	System	21 Aug 2020 15:31:07
User entered empty.	System	21 Aug 2020 15:30:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered '60' reason for change: Data Entry Error	(b) (4)	
	Sandra Francisco (b) (4)	21 Aug 2020 15:31:07
User entered empty.	(b) (4)	
	Sandra Francisco (b) (4)	21 Aug 2020 15:30:34
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered 'mmHg'	System	21 Aug 2020 15:31:07
User entered empty.	System	21 Aug 2020 15:30:34

US3862044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:38:20

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
	(b) (4)	
User entered '69' in	Sandra Francisco (b) (4)	21 Aug 2020 15:30:34
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:38:20

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered '179.6' lb	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:30:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User accepted default value 'Post-Dose (POSTDOSE)'	Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:30:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Aug 2020 17:25:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 17:25:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Chanei Henry (b) (4)	21 Aug 2020 17:25:20
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Aug 2020 15:30:34
User entered empty.	System	21 Aug 2020 15:30:34
	Sandra Francisco (b) (4)	21 Aug 2020 15:30:34
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered '21 Aug 2020' reason for change: Data Entry Error	(b) (4)	21 Aug 2020 17:25:20
User entered empty.	Chanei Henry (b) (4)	21 Aug 2020 17:25:20
	(b) (4)	
	Sandra Francisco (b) (4)	21 Aug 2020 15:30:34
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered '10:54' reason for change: Data Entry Error	(b) (4)	21 Aug 2020 17:25:20
User entered empty.	Chanei Henry (b) (4)	21 Aug 2020 15:30:34
	(b) (4)	
	Sandra Francisco (b) (4)	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered '21 Aug 2020 10:54'	System	21 Aug 2020 17:25:20
User entered empty.	System	21 Aug 2020 15:30:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered '97.6' F reason for change: Data Entry Error	(b) (4) Chanei Henry (b) (4)	21 Aug 2020 17:25:20
User entered empty.	(b) (4) Sandra Francisco (b) (4)	21 Aug 2020 15:30:34
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4)	21 Aug 2020 17:25:20
User entered empty.	Chanei Henry (b) (4)	21 Aug 2020 15:30:34
	(b) (4)	
	Sandra Francisco (b) (4)	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
	(b) (4)	
User entered 'Temporal' reason for change: Data Entry Error	Chanei Henry (b) (4)	21 Aug 2020 17:25:20
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	21 Aug 2020 15:30:34
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
	(b) (4)	
User entered '59' reason for change: Data Entry Error	Chanei Henry (b) (4)	21 Aug 2020 17:25:20
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	21 Aug 2020 15:30:34
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered 'bpm'	System	21 Aug 2020 17:25:20
User entered empty.	System	21 Aug 2020 15:30:34

US3862044

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered '16' reason for change: Data Entry Error	(b) (4) Chanei Henry (b) (4)	21 Aug 2020 17:25:20
User entered empty.	(b) (4) Sandra Francisco (b) (4)	21 Aug 2020 15:30:34
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered 'breaths/min'	System	21 Aug 2020 17:25:20
User entered empty.	System	21 Aug 2020 15:30:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered '122' reason for change: Data Entry Error	(b) (4) Chanei Henry (b) (4)	21 Aug 2020 17:25:20
User entered empty.	(b) (4) Sandra Francisco (b) (4)	21 Aug 2020 15:30:34
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered 'mmHg'	System	21 Aug 2020 17:25:20
User entered empty.	System	21 Aug 2020 15:30:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered '73' reason for change: Data Entry Error	(b) (4) Chanei Henry (b) (4)	21 Aug 2020 17:25:20
User entered empty.	(b) (4) Sandra Francisco (b) (4)	21 Aug 2020 15:30:34
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered 'mmHg'	System	21 Aug 2020 17:25:20
User entered empty.	System	21 Aug 2020 15:30:34

US3862044

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:38:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
	(b) (4)	
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	21 Aug 2020 15:30:15
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:38:20

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered '21 Aug 2020'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:30:15

US3862044

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:38:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	(b) (4)	21 Aug 2020 15:29:34
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	21 Aug 2020 15:29:34
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	21 Aug 2020 15:29:09
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	21 Aug 2020 15:29:09

US3862044

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:38:20

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered empty.	(b) (4)	
	Sandra Francisco (b) (4)	21 Aug 2020 15:29:09
	(b) (4)	

US3862044

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:38:20

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 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered empty.	(b) (4)	
	Sandra Francisco (b) (4)	21 Aug 2020 15:29:09
	(b) (4)	

US3862044

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:38:20

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered 'MRNA-1273 OR PLACEBO'	System	21 Aug 2020 15:29:09

US3862044

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
	(b) (4)	
User entered '21 Aug 2020'	Sandra Francisco (b) (4)	21 Aug 2020 15:29:09
	(b) (4)	

US3862044

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered '10:21' reason for change: Data Entry Error	(b) (4)	
	Sandra Francisco (b) (4)	21 Aug 2020 15:29:34
User entered empty.	(b) (4)	
	Sandra Francisco (b) (4)	21 Aug 2020 15:29:09
	(b) (4)	

US3862044

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered '21 Aug 2020 10:21'	System	21 Aug 2020 15:29:34
User entered empty.	System	21 Aug 2020 15:29:09

US3862044

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
	(b) (4)	
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	Sandra Francisco (b) (4)	21 Aug 2020 15:29:34
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	21 Aug 2020 15:29:09
	(b) (4)	

US3862044

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered 'ONCE'	System	21 Aug 2020 15:29:09

US3862044

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered 'INTRAMUSCULAR'	System	21 Aug 2020 15:29:09

US3862044

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:38:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:29:57

US3862044

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:38:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered '21 Aug 2020'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:29:57

US3862044

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:38:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered '09:27'	(b) (4)	
	Sandra Francisco (b) (4)	21 Aug 2020 15:29:57
	(b) (4)	

US3862044

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered '21 Aug 2020 09:27'	System	21 Aug 2020 15:29:57

US3862044

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:38:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered '21 Aug 2020'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:30:09

US3862044

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:38:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:30:09

US3862044

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:38:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
	(b) (4)	
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	21 Aug 2020 15:30:09
	(b) (4)	

US3862044

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:38:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered '09:11'	(b) (4) Sandra Francisco (b) (4)	21 Aug 2020 15:30:09

US3862044

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered '21 Aug 2020 09:11'	System	21 Aug 2020 15:30:09

US3862044

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:38:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:30:09

US3862044

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:38:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
	(b) (4)	
User entered 'No (N)'	Sandra Francisco (b) (4)	21 Aug 2020 15:30:09
	(b) (4)	

US3862044

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:38:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered empty.	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:30:09

US3862044

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered empty.	System	21 Aug 2020 15:30:09

US3862044

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:26
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4) (b) (4)	21 Aug 2020 17:07:15

US3862044

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:38:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered '1'	System	21 Aug 2020 17:07:15

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
Data entry locked.	System	21 Aug 2020 15:29:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:38:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-21T10:57:35', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '6ecdbdcd-cc36-4f8d-b0d0-a75ed2655040' User entered 'Yes (Y)'	System	21 Aug 2020 15:57:52
	System	21 Aug 2020 15:57:52

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:38:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-21T10:57:41', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '6ecdbdcd-cc36-4f8d-b0d0-a75ed2655040' User entered '97.6'	System	21 Aug 2020 15:57:52
	System	21 Aug 2020 15:57:52

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-21T10:57:45', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '6ecdbdcd-cc36-4f8d-b0d0-a75ed2655040'	System	21 Aug 2020 15:57:52
User entered 'No (N)'	System	21 Aug 2020 15:57:52

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:38:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-21T10:57:50', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '6ecdbdcd-cc36-4f8d-b0d0-a75ed2655040' User entered '21 Aug 2020 10:57'	System	21 Aug 2020 15:57:52
	System	21 Aug 2020 15:57:52

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:38:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '21 Aug 2020 10:41'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:38:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '21 Aug 2020 13:11'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
Data entry locked.	System	21 Aug 2020 15:29:34
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:38:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-22T09:38:46', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '9b1c4ce2-6c47-4c40-befc-01f3f78686cf' User entered 'Yes (Y)'	System	22 Aug 2020 14:39:05
	System	22 Aug 2020 14:39:05

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:38:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-22T09:38:52', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '9b1c4ce2-6c47-4c40-befc-01f3f78686cf' User entered '97.5'	System	22 Aug 2020 14:39:05
	System	22 Aug 2020 14:39:05

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-22T09:38:57', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '9b1c4ce2-6c47-4c40-befc-01f3f78686cf' User entered 'No (N)'	System	22 Aug 2020 14:39:05
	System	22 Aug 2020 14:39:05

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:38:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-22T09:39:03', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '9b1c4ce2-6c47-4c40-befc-01f3f78686cf' User entered '22 Aug 2020 09:39'	System	22 Aug 2020 14:39:05
	System	22 Aug 2020 14:39:05

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:38:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '21 Aug 2020 14:06'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:38:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
Data entry locked.	System	21 Aug 2020 15:29:34
User entered 'Day 2'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:38:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-22T12:07:36', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '89ce0343-8ad8-4e0a-b69d-209214509d34'	System	22 Aug 2020 17:07:49
User entered 'Yes (Y)'	System	22 Aug 2020 17:07:49

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:38:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-22T12:07:42', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '89ce0343-8ad8-4e0a-b69d-209214509d34' User entered '97.5'	System	22 Aug 2020 17:07:49
	System	22 Aug 2020 17:07:49

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-22T12:07:45', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '89ce0343-8ad8-4e0a-b69d-209214509d34'	System	22 Aug 2020 17:07:49
User entered 'No (N)'	System	22 Aug 2020 17:07:49

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:38:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-22T12:07:48', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '89ce0343-8ad8-4e0a-b69d-209214509d34'	System	22 Aug 2020 17:07:49
User entered '22 Aug 2020 12:07'	System	22 Aug 2020 17:07:49

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:38:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:38:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
Data entry locked.	System	21 Aug 2020 15:29:34
User entered 'Day 3'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:38:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-23T20:39:29', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '7a1bc863-44e6-4b8e-b5d2-3a188bb00788' User entered 'Yes (Y)'	System	24 Aug 2020 01:39:43
	System	24 Aug 2020 01:39:43

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:38:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-23T20:39:34', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '7a1bc863-44e6-4b8e-b5d2-3a188bb00788' User entered '97.6'	System	24 Aug 2020 01:39:43
	System	24 Aug 2020 01:39:43

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-23T20:39:38', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '7a1bc863-44e6-4b8e-b5d2-3a188bb00788' User entered 'No (N)'	System	24 Aug 2020 01:39:43
	System	24 Aug 2020 01:39:43

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:38:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-23T20:39:42', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '7a1bc863-44e6-4b8e-b5d2-3a188bb00788' User entered '23 Aug 2020 20:39'	System	24 Aug 2020 01:39:43
	System	24 Aug 2020 01:39:43

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:38:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:38:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
Data entry locked.	System	21 Aug 2020 15:29:34
User entered 'Day 4'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:38:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-24T12:00:35', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'e2d6e899-1e82-430f-82b0-a246f6c0afa5' User entered 'Yes (Y)'	System	24 Aug 2020 17:00:50
	System	24 Aug 2020 17:00:50

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:38:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-24T12:00:40', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'e2d6e899-1e82-430f-82b0-a246f6c0afa5' User entered '97.6'	System	24 Aug 2020 17:00:50
	System	24 Aug 2020 17:00:50

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-24T12:00:43', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'e2d6e899-1e82-430f-82b0-a246f6c0afa5'	System	24 Aug 2020 17:00:50
User entered 'No (N)'	System	24 Aug 2020 17:00:50

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:38:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-24T12:00:46', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'e2d6e899-1e82-430f-82b0-a246f6c0afa5' User entered '24 Aug 2020 12:00'	System	24 Aug 2020 17:00:50
	System	24 Aug 2020 17:00:50

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:38:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:38:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
Data entry locked.	System	21 Aug 2020 15:29:34
User entered 'Day 5'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:38:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-25T12:00:18', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'a7ebc15c-d6ae-410a-bac5-35e1c6fcb263' User entered 'Yes (Y)'	System	25 Aug 2020 17:00:37
	System	25 Aug 2020 17:00:37

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:38:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-25T12:00:25', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'a7ebc15c-d6ae-410a-bac5-35e1c6fcb263' User entered '97.5'	System	25 Aug 2020 17:00:37
	System	25 Aug 2020 17:00:37

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-25T12:00:27', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'a7ebc15c-d6ae-410a-bac5-35e1c6fcb263'	System	25 Aug 2020 17:00:37
User entered 'No (N)'	System	25 Aug 2020 17:00:37

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:38:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-25T12:00:31', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'a7ebc15c-d6ae-410a-bac5-35e1c6fcb263'	System	25 Aug 2020 17:00:37
User entered '25 Aug 2020 12:00'	System	25 Aug 2020 17:00:37

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:38:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:38:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
Data entry locked.	System	21 Aug 2020 15:29:34
User entered 'Day 6'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:38:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-26T12:17:15', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '4829b4fc-4492-483e-ae8e-1793bb4636a8' User entered 'Yes (Y)'	System	26 Aug 2020 17:17:28
	System	26 Aug 2020 17:17:28

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:38:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-26T12:17:20', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '4829b4fc-4492-483e-ae8e-1793bb4636a8' User entered '97.5'	System	26 Aug 2020 17:17:28
	System	26 Aug 2020 17:17:28

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-26T12:17:24', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '4829b4fc-4492-483e-ae8e-1793bb4636a8' User entered 'No (N)'	System	26 Aug 2020 17:17:28
	System	26 Aug 2020 17:17:28

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:38:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-26T12:17:26', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '4829b4fc-4492-483e-ae8e-1793bb4636a8' User entered '26 Aug 2020 12:17'	System	26 Aug 2020 17:17:28
	System	26 Aug 2020 17:17:28

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:38:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:38:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
Data entry locked.	System	21 Aug 2020 15:29:34
User entered 'Day 7'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:38:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-27T12:03:31', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '372fd08b-c21b-4981-bf7f-365a886159de' User entered 'Yes (Y)'	System	27 Aug 2020 17:04:13
	System	27 Aug 2020 17:04:13

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:38:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-27T12:03:35', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '372fd08b-c21b-4981-bf7f-365a886159de' User entered '97.7'	System	27 Aug 2020 17:04:13
	System	27 Aug 2020 17:04:13

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-27T12:03:37', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '372fd08b-c21b-4981-bf7f-365a886159de' User entered 'No (N)'	System	27 Aug 2020 17:04:13
	System	27 Aug 2020 17:04:13

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:38:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-27T12:03:40', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '372fd08b-c21b-4981-bf7f-365a886159de' User entered '27 Aug 2020 12:03'	System	27 Aug 2020 17:04:13
	System	27 Aug 2020 17:04:13

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:38:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:38:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
Data entry locked.	System	21 Aug 2020 15:29:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:38:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-21T10:57:58', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '0c99d076-4eed-405c-ba8c-e4ecd044c5c5'	System	21 Aug 2020 15:58:22
User entered 'None (1)'	System	21 Aug 2020 15:58:22

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:38:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-21T10:58:00', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '0c99d076-4eed-405c-ba8c-e4ecd044c5c5' User entered 'No (N)'	System	21 Aug 2020 15:58:22
	System	21 Aug 2020 15:58:22

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-21T10:58:03', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '0c99d076-4eed-405c-ba8c-e4ecd044c5c5' User entered 'No (N)'	System	21 Aug 2020 15:58:22
	System	21 Aug 2020 15:58:22

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:38:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-21T10:58:16', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '0c99d076-4eed-405c-ba8c-e4ecd044c5c5'	System	21 Aug 2020 15:58:22
User entered 'None (1)'	System	21 Aug 2020 15:58:22

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:38:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-21T10:58:19', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '0c99d076-4eed-405c-ba8c-e4ecd044c5c5' User entered '21 Aug 2020 10:58'	System	21 Aug 2020 15:58:22
	System	21 Aug 2020 15:58:22

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:38:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '21 Aug 2020 10:41'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:38:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '21 Aug 2020 13:11'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
Data entry locked.	System	21 Aug 2020 15:29:34
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:38:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-22T09:39:16', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '1fa8308c-4051-4163-b0b4-5a758ff4f810'	System	22 Aug 2020 14:39:37
User entered 'None (1)'	System	22 Aug 2020 14:39:37

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:38:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-22T09:39:19', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '1fa8308c-4051-4163-b0b4-5a758ff4f810'	System	22 Aug 2020 14:39:37
User entered 'No (N)'	System	22 Aug 2020 14:39:37

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-22T09:39:22', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '1fa8308c-4051-4163-b0b4-5a758ff4f810'	System	22 Aug 2020 14:39:37
User entered 'No (N)'	System	22 Aug 2020 14:39:37

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:38:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-22T09:39:30', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '1fa8308c-4051-4163-b0b4-5a758ff4f810'	System	22 Aug 2020 14:39:37
User entered 'None (1)'	System	22 Aug 2020 14:39:37

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:38:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-22T09:39:33', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '1fa8308c-4051-4163-b0b4-5a758ff4f810' User entered '22 Aug 2020 09:39'	System	22 Aug 2020 14:39:37
	System	22 Aug 2020 14:39:37

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:38:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '21 Aug 2020 14:06'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:38:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
Data entry locked.	System	21 Aug 2020 15:29:34
User entered 'Day 2'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:38:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-22T12:07:51', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'a0672e1f-1822-4e66-a1f7-276187fd4a4e' User entered 'None (1)'	System	22 Aug 2020 17:08:02
	System	22 Aug 2020 17:08:02

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:38:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-22T12:07:54', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'a0672e1f-1822-4e66-a1f7-276187fd4a4e' User entered 'No (N)'	System	22 Aug 2020 17:08:02
	System	22 Aug 2020 17:08:02

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-22T12:07:55', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'a0672e1f-1822-4e66-a1f7-276187fd4a4e' User entered 'No (N)'	System	22 Aug 2020 17:08:02
	System	22 Aug 2020 17:08:02

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:38:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-22T12:07:57', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'a0672e1f-1822-4e66-a1f7-276187fd4a4e' User entered 'None (1)'	System	22 Aug 2020 17:08:02
	System	22 Aug 2020 17:08:02

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:38:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-22T12:08:01', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'a0672e1f-1822-4e66-a1f7-276187fd4a4e' User entered '22 Aug 2020 12:08'	System	22 Aug 2020 17:08:02
	System	22 Aug 2020 17:08:02

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:38:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:38:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
Data entry locked.	System	21 Aug 2020 15:29:34
User entered 'Day 3'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:38:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-23T20:39:52', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'f3098c13-b437-4a5c-82fe-0d953c371790' User entered 'None (1)'	System	24 Aug 2020 01:40:06
	System	24 Aug 2020 01:40:06

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:38:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-23T20:39:55', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'f3098c13-b437-4a5c-82fe-0d953c371790'	System	24 Aug 2020 01:40:06
User entered 'No (N)'	System	24 Aug 2020 01:40:06

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-23T20:39:57', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'f3098c13-b437-4a5c-82fe-0d953c371790' User entered 'No (N)'	System	24 Aug 2020 01:40:06
	System	24 Aug 2020 01:40:06

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:38:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-23T20:39:59', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'f3098c13-b437-4a5c-82fe-0d953c371790' User entered 'None (1)'	System	24 Aug 2020 01:40:06
	System	24 Aug 2020 01:40:06

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:38:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-23T20:40:03', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'f3098c13-b437-4a5c-82fe-0d953c371790' User entered '23 Aug 2020 20:40'	System	24 Aug 2020 01:40:06
	System	24 Aug 2020 01:40:06

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:38:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:38:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
Data entry locked.	System	21 Aug 2020 15:29:34
User entered 'Day 4'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:38:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-24T12:00:56', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'faeb6d9a-b51b-4302-8f96-a9f6f46f3e67'	System	24 Aug 2020 17:01:22
User entered 'None (1)'	System	24 Aug 2020 17:01:22

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:38:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-24T12:00:59', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'faeb6d9a-b51b-4302-8f96-a9f6f46f3e67'	System	24 Aug 2020 17:01:22
User entered 'No (N)'	System	24 Aug 2020 17:01:22

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-24T12:01:04', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'faeb6d9a-b51b-4302-8f96-a9f6f46f3e67' User entered 'No (N)'	System	24 Aug 2020 17:01:22
	System	24 Aug 2020 17:01:22

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:38:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-24T12:01:08', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'faeb6d9a-b51b-4302-8f96-a9f6f46f3e67'	System	24 Aug 2020 17:01:22
User entered 'None (1)'	System	24 Aug 2020 17:01:22

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:38:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-24T12:01:13', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'faeb6d9a-b51b-4302-8f96-a9f6f46f3e67' User entered '24 Aug 2020 12:01'	System	24 Aug 2020 17:01:22
	System	24 Aug 2020 17:01:22

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:38:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:38:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
Data entry locked.	System	21 Aug 2020 15:29:34
User entered 'Day 5'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:38:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-25T12:00:34', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'e5c77c91-cc85-487d-aa0d-8a01a5d06069'	System	25 Aug 2020 17:00:49
User entered 'None (1)'	System	25 Aug 2020 17:00:49

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:38:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-25T12:00:37', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'e5c77c91-cc85-487d-aa0d-8a01a5d06069'	System	25 Aug 2020 17:00:49
User entered 'No (N)'	System	25 Aug 2020 17:00:49

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-25T12:00:38', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'e5c77c91-cc85-487d-aa0d-8a01a5d06069'	System	25 Aug 2020 17:00:49
User entered 'No (N)'	System	25 Aug 2020 17:00:49

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:38:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-25T12:00:41', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'e5c77c91-cc85-487d-aa0d-8a01a5d06069'	System	25 Aug 2020 17:00:49
User entered 'None (1)'	System	25 Aug 2020 17:00:49

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:38:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-25T12:00:43', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'e5c77c91-cc85-487d-aa0d-8a01a5d06069'	System	25 Aug 2020 17:00:49
User entered '25 Aug 2020 12:00'	System	25 Aug 2020 17:00:49

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:38:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:38:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
Data entry locked.	System	21 Aug 2020 15:29:34
User entered 'Day 6'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:38:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-26T12:17:31', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '40db6f40-5b79-4a62-b341-321e762875dd'	System	26 Aug 2020 17:17:42
User entered 'None (1)'	System	26 Aug 2020 17:17:42

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:38:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-26T12:17:34', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '40db6f40-5b79-4a62-b341-321e762875dd' User entered 'No (N)'	System	26 Aug 2020 17:17:42
	System	26 Aug 2020 17:17:42

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-26T12:17:35', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '40db6f40-5b79-4a62-b341-321e762875dd' User entered 'No (N)'	System	26 Aug 2020 17:17:42
	System	26 Aug 2020 17:17:42

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:38:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-26T12:17:38', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '40db6f40-5b79-4a62-b341-321e762875dd' User entered 'None (1)'	System	26 Aug 2020 17:17:42
	System	26 Aug 2020 17:17:42

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:38:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-26T12:17:40', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '40db6f40-5b79-4a62-b341-321e762875dd' User entered '26 Aug 2020 12:17'	System	26 Aug 2020 17:17:42
	System	26 Aug 2020 17:17:42

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:38:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:38:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
Data entry locked.	System	21 Aug 2020 15:29:34
User entered 'Day 7'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:38:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-27T12:03:44', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'b85a4c1e-6904-46ee-b9e7-ea932b993c09'	System	27 Aug 2020 17:04:17
User entered 'None (1)'	System	27 Aug 2020 17:04:17

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:38:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-27T12:03:46', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'b85a4c1e-6904-46ee-b9e7-ea932b993c09'	System	27 Aug 2020 17:04:17
User entered 'No (N)'	System	27 Aug 2020 17:04:17

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-27T12:03:47', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'b85a4c1e-6904-46ee-b9e7-ea932b993c09' User entered 'No (N)'	System	27 Aug 2020 17:04:17
	System	27 Aug 2020 17:04:17

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:38:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-27T12:03:50', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'b85a4c1e-6904-46ee-b9e7-ea932b993c09'	System	27 Aug 2020 17:04:17
User entered 'None (1)'	System	27 Aug 2020 17:04:17

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:38:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-27T12:03:53', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'b85a4c1e-6904-46ee-b9e7-ea932b993c09' User entered '27 Aug 2020 12:03'	System	27 Aug 2020 17:04:17
	System	27 Aug 2020 17:04:17

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:38:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:38:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
Data entry locked.	System	21 Aug 2020 15:29:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:38:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-21T12:56:21', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '1fc652fd-fdb7-429e-93b8-e78bed200f4f' User entered 'None (0)'	System	21 Aug 2020 17:56:40
	System	21 Aug 2020 17:56:40

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:38:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-21T12:56:23', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '1fc652fd-fdb7-429e-93b8-e78bed200f4f' User entered 'None (0)'	System	21 Aug 2020 17:56:40
	System	21 Aug 2020 17:56:40

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:38:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-21T12:56:25', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '1fc652fd-fdb7-429e-93b8-e78bed200f4f' User entered 'None (0)'	System	21 Aug 2020 17:56:40
	System	21 Aug 2020 17:56:40

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:38:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-21T12:56:27', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '1fc652fd-fdb7-429e-93b8-e78bed200f4f' User entered 'None (0)'	System	21 Aug 2020 17:56:40
	System	21 Aug 2020 17:56:40

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:38:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-21T12:56:29', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '1fc652fd-fdb7-429e-93b8-e78bed200f4f' User entered 'None (0)'	System	21 Aug 2020 17:56:40
	System	21 Aug 2020 17:56:40

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:38:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-21T12:56:31', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '1fc652fd-fdb7-429e-93b8-e78bed200f4f' User entered 'None (0)'	System	21 Aug 2020 17:56:40
	System	21 Aug 2020 17:56:40

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:38:20

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)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-21T12:56:33', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '1fc652fd-fdb7-429e-93b8-e78bed200f4f' User entered 'No (N)'	System	21 Aug 2020 17:56:40
	System	21 Aug 2020 17:56:40

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:38:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-21T12:56:38', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '1fc652fd-fdb7-429e-93b8-e78bed200f4f' User entered '21 Aug 2020 12:56'	System	21 Aug 2020 17:56:40
	System	21 Aug 2020 17:56:40

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:38:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '21 Aug 2020 10:41'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:38:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '21 Aug 2020 13:11'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
Data entry locked.	System	21 Aug 2020 15:29:34
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:38:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-22T09:39:38', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '7829bde0-971b-4539-9544-e01e67b6a2cf' User entered 'None (0)'	System	22 Aug 2020 14:39:59
	System	22 Aug 2020 14:39:59

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:38:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-22T09:39:41', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '7829bde0-971b-4539-9544-e01e67b6a2cf' User entered 'None (0)'	System	22 Aug 2020 14:39:59
	System	22 Aug 2020 14:39:59

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:38:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-22T09:39:43', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '7829bde0-971b-4539-9544-e01e67b6a2cf' User entered 'None (0)'	System	22 Aug 2020 14:39:59
	System	22 Aug 2020 14:39:59

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:38:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-22T09:39:45', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '7829bde0-971b-4539-9544-e01e67b6a2cf' User entered 'None (0)'	System	22 Aug 2020 14:39:59
	System	22 Aug 2020 14:39:59

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:38:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-22T09:39:47', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '7829bde0-971b-4539-9544-e01e67b6a2cf' User entered 'None (0)'	System	22 Aug 2020 14:39:59
	System	22 Aug 2020 14:39:59

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:38:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-22T09:39:48', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '7829bde0-971b-4539-9544-e01e67b6a2cf' User entered 'None (0)'	System	22 Aug 2020 14:39:59
	System	22 Aug 2020 14:39:59

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:38:20

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)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-22T09:39:51', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '7829bde0-971b-4539-9544-e01e67b6a2cf' User entered 'No (N)'	System	22 Aug 2020 14:39:59
	System	22 Aug 2020 14:39:59

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:38:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-22T09:39:57', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '7829bde0-971b-4539-9544-e01e67b6a2cf' User entered '22 Aug 2020 09:39'	System	22 Aug 2020 14:39:59
	System	22 Aug 2020 14:39:59

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:38:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '21 Aug 2020 14:06'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:38:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
Data entry locked.	System	21 Aug 2020 15:29:34
User entered 'Day 2'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:38:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-22T12:08:04', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'b26a8361-9ea5-4993-bca5-87a49ff1422a' User entered 'None (0)'	System	22 Aug 2020 17:08:21
	System	22 Aug 2020 17:08:21

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:38:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-22T12:08:05', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'b26a8361-9ea5-4993-bca5-87a49ff1422a' User entered 'None (0)'	System	22 Aug 2020 17:08:21
	System	22 Aug 2020 17:08:21

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:38:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-22T12:08:07', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'b26a8361-9ea5-4993-bca5-87a49ff1422a' User entered 'None (0)'	System	22 Aug 2020 17:08:21
	System	22 Aug 2020 17:08:21

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:38:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-22T12:08:08', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'b26a8361-9ea5-4993-bca5-87a49ff1422a' User entered 'None (0)'	System	22 Aug 2020 17:08:21
	System	22 Aug 2020 17:08:21

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:38:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-22T12:08:10', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'b26a8361-9ea5-4993-bca5-87a49ff1422a' User entered 'None (0)'	System	22 Aug 2020 17:08:21
	System	22 Aug 2020 17:08:21

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:38:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-22T12:08:13', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'b26a8361-9ea5-4993-bca5-87a49ff1422a' User entered 'None (0)'	System	22 Aug 2020 17:08:21
	System	22 Aug 2020 17:08:21

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:38:20

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)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-22T12:08:15', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'b26a8361-9ea5-4993-bca5-87a49ff1422a'	System	22 Aug 2020 17:08:21
User entered 'No (N)'	System	22 Aug 2020 17:08:21

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:38:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-22T12:08:18', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'b26a8361-9ea5-4993-bca5-87a49ff1422a' User entered '22 Aug 2020 12:08'	System	22 Aug 2020 17:08:21
	System	22 Aug 2020 17:08:21

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:38:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:38:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
Data entry locked.	System	21 Aug 2020 15:29:34
User entered 'Day 3'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:38:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-23T20:40:07', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '54bef6d1-4036-4119-81a6-23ed994eca1f' User entered 'None (0)'	System	24 Aug 2020 01:40:22
	System	24 Aug 2020 01:40:22

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:38:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-23T20:40:09', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '54bef6d1-4036-4119-81a6-23ed994eca1f' User entered 'None (0)'	System	24 Aug 2020 01:40:22
	System	24 Aug 2020 01:40:22

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:38:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-23T20:40:11', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '54bef6d1-4036-4119-81a6-23ed994eca1f' User entered 'None (0)'	System	24 Aug 2020 01:40:22
	System	24 Aug 2020 01:40:22

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:38:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-23T20:40:12', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '54bef6d1-4036-4119-81a6-23ed994eca1f' User entered 'None (0)'	System	24 Aug 2020 01:40:22
	System	24 Aug 2020 01:40:22

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:38:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-23T20:40:14', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '54bef6d1-4036-4119-81a6-23ed994eca1f' User entered 'None (0)'	System	24 Aug 2020 01:40:22
	System	24 Aug 2020 01:40:22

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:38:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-23T20:40:16', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '54bef6d1-4036-4119-81a6-23ed994eca1f' User entered 'None (0)'	System	24 Aug 2020 01:40:22
	System	24 Aug 2020 01:40:22

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:38:20

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)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-23T20:40:18', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '54bef6d1-4036-4119-81a6-23ed994eca1f' User entered 'No (N)'	System	24 Aug 2020 01:40:22
	System	24 Aug 2020 01:40:22

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:38:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-23T20:40:20', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '54bef6d1-4036-4119-81a6-23ed994eca1f' User entered '23 Aug 2020 20:40'	System	24 Aug 2020 01:40:22
	System	24 Aug 2020 01:40:22

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:38:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:38:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
Data entry locked.	System	21 Aug 2020 15:29:34
User entered 'Day 4'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:38:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-24T12:01:17', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '2b4df222-e94d-47cf-be2b-6c56c6f7f184' User entered 'None (0)'	System	24 Aug 2020 17:01:46
	System	24 Aug 2020 17:01:46

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:38:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-24T12:01:19', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '2b4df222-e94d-47cf-be2b-6c56c6f7f184' User entered 'None (0)'	System	24 Aug 2020 17:01:46
	System	24 Aug 2020 17:01:46

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:38:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-24T12:01:21', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '2b4df222-e94d-47cf-be2b-6c56c6f7f184' User entered 'None (0)'	System	24 Aug 2020 17:01:46
	System	24 Aug 2020 17:01:46

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:38:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-24T12:01:23', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '2b4df222-e94d-47cf-be2b-6c56c6f7f184' User entered 'None (0)'	System	24 Aug 2020 17:01:46
	System	24 Aug 2020 17:01:46

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:38:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-24T12:01:25', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '2b4df222-e94d-47cf-be2b-6c56c6f7f184' User entered 'None (0)'	System	24 Aug 2020 17:01:46
	System	24 Aug 2020 17:01:46

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:38:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-24T12:01:27', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '2b4df222-e94d-47cf-be2b-6c56c6f7f184' User entered 'None (0)'	System	24 Aug 2020 17:01:46
	System	24 Aug 2020 17:01:46

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:38:20

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)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-24T12:01:29', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '2b4df222-e94d-47cf-be2b-6c56c6f7f184'	System	24 Aug 2020 17:01:46
User entered 'No (N)'	System	24 Aug 2020 17:01:46

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:38:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-24T12:01:33', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '2b4df222-e94d-47cf-be2b-6c56c6f7f184' User entered '24 Aug 2020 12:01'	System	24 Aug 2020 17:01:46
	System	24 Aug 2020 17:01:46

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:38:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:38:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
Data entry locked.	System	21 Aug 2020 15:29:34
User entered 'Day 5'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:38:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-25T12:00:47', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'de8f8b1d-db9d-4b75-9496-67abb14e279b' User entered 'None (0)'	System	25 Aug 2020 17:01:13
	System	25 Aug 2020 17:01:13

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:38:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-25T12:00:48', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'de8f8b1d-db9d-4b75-9496-67abb14e279b' User entered 'None (0)'	System	25 Aug 2020 17:01:13
	System	25 Aug 2020 17:01:13

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:38:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-25T12:00:49', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'de8f8b1d-db9d-4b75-9496-67abb14e279b' User entered 'None (0)'	System	25 Aug 2020 17:01:13
	System	25 Aug 2020 17:01:13

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:38:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-25T12:00:51', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'de8f8b1d-db9d-4b75-9496-67abb14e279b' User entered 'None (0)'	System	25 Aug 2020 17:01:13
	System	25 Aug 2020 17:01:13

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:38:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-25T12:00:53', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'de8f8b1d-db9d-4b75-9496-67abb14e279b' User entered 'None (0)'	System	25 Aug 2020 17:01:13
	System	25 Aug 2020 17:01:13

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:38:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-25T12:00:55', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'de8f8b1d-db9d-4b75-9496-67abb14e279b' User entered 'None (0)'	System	25 Aug 2020 17:01:13
	System	25 Aug 2020 17:01:13

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:38:20

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)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-25T12:00:56', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'de8f8b1d-db9d-4b75-9496-67abb14e279b' User entered 'No (N)'	System	25 Aug 2020 17:01:13
	System	25 Aug 2020 17:01:13

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:38:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-25T12:01:00', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'de8f8b1d-db9d-4b75-9496-67abb14e279b' User entered '25 Aug 2020 12:01'	System	25 Aug 2020 17:01:13
	System	25 Aug 2020 17:01:13

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:38:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:38:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
Data entry locked.	System	21 Aug 2020 15:29:34
User entered 'Day 6'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:38:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-26T12:17:44', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '314e0dd4-fc63-4325-805f-99bef9285760' User entered 'None (0)'	System	26 Aug 2020 17:18:10
	System	26 Aug 2020 17:18:10

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:38:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-26T12:17:53', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '314e0dd4-fc63-4325-805f-99bef9285760' User entered 'None (0)'	System	26 Aug 2020 17:18:10
	System	26 Aug 2020 17:18:10

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:38:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-26T12:17:56', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '314e0dd4-fc63-4325-805f-99bef9285760' User entered 'None (0)'	System	26 Aug 2020 17:18:10
	System	26 Aug 2020 17:18:10

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:38:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-26T12:17:59', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '314e0dd4-fc63-4325-805f-99bef9285760' User entered 'None (0)'	System	26 Aug 2020 17:18:10
	System	26 Aug 2020 17:18:10

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:38:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-26T12:18:01', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '314e0dd4-fc63-4325-805f-99bef9285760' User entered 'None (0)'	System	26 Aug 2020 17:18:10
	System	26 Aug 2020 17:18:10

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:38:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-26T12:18:03', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '314e0dd4-fc63-4325-805f-99bef9285760' User entered 'None (0)'	System	26 Aug 2020 17:18:10
	System	26 Aug 2020 17:18:10

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:38:20

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)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-26T12:18:05', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '314e0dd4-fc63-4325-805f-99bef9285760' User entered 'No (N)'	System	26 Aug 2020 17:18:10
	System	26 Aug 2020 17:18:10

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:38:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-26T12:18:08', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '314e0dd4-fc63-4325-805f-99bef9285760' User entered '26 Aug 2020 12:18'	System	26 Aug 2020 17:18:10
	System	26 Aug 2020 17:18:10

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:38:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:38:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
Data entry locked.	System	21 Aug 2020 15:29:34
User entered 'Day 7'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:38:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-27T12:03:56', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '22499fa4-701c-4f84-b8ff-2b36dbc37e69' User entered 'None (0)'	System	27 Aug 2020 17:04:24
	System	27 Aug 2020 17:04:24

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:38:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-27T12:03:57', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '22499fa4-701c-4f84-b8ff-2b36dbc37e69' User entered 'None (0)'	System	27 Aug 2020 17:04:24
	System	27 Aug 2020 17:04:24

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:38:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-27T12:03:59', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '22499fa4-701c-4f84-b8ff-2b36dbc37e69' User entered 'None (0)'	System	27 Aug 2020 17:04:24
	System	27 Aug 2020 17:04:24

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:38:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-27T12:04:01', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '22499fa4-701c-4f84-b8ff-2b36dbc37e69' User entered 'None (0)'	System	27 Aug 2020 17:04:24
	System	27 Aug 2020 17:04:24

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:38:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-27T12:04:03', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '22499fa4-701c-4f84-b8ff-2b36dbc37e69' User entered 'None (0)'	System	27 Aug 2020 17:04:24
	System	27 Aug 2020 17:04:24

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:38:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-27T12:04:04', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '22499fa4-701c-4f84-b8ff-2b36dbc37e69' User entered 'None (0)'	System	27 Aug 2020 17:04:24
	System	27 Aug 2020 17:04:24

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:38:20

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)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-27T12:04:07', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '22499fa4-701c-4f84-b8ff-2b36dbc37e69' User entered 'Yes (Y)'	System	27 Aug 2020 17:04:24
	System	27 Aug 2020 17:04:24

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:38:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-08-27T12:04:11', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '22499fa4-701c-4f84-b8ff-2b36dbc37e69' User entered '27 Aug 2020 12:04'	System	27 Aug 2020 17:04:24
	System	27 Aug 2020 17:04:24

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:38:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 15:29:34

US3862044

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:38:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 15:29:34

US3862044

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered 'Yes (Y)'	(b) (4) Coni Cheesman (b) (4)	29 Aug 2020 23:43:39

US3862044

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:20

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered '28 Aug 2020'	(b) (4) Coni Cheesman (b) (4)	29 Aug 2020 23:43:39

US3862044

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Coni Cheesman (b) (4)	29 Aug 2020 23:43:39

US3862044

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered empty.	(b) (4) Coni Cheesman (b) (4)	29 Aug 2020 23:43:39

US3862044

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:19
User entered 'Yes (Y)'	(b) (4) Coni Cheesman (b) (4)	04 Sep 2020 23:52:27

US3862044

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered '1'	System	04 Sep 2020 23:52:27

US3862044

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:19
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	(b) (4)	04 Sep 2020 23:53:25
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	04 Sep 2020 23:52:50
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	04 Sep 2020 23:52:50

US3862044

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:19
User entered '4 Sep 2020'	(b) (4) Coni Cheesman (b) (4)	04 Sep 2020 23:52:50

US3862044

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	04 Sep 2020 23:53:25
reason for change: Data Entry Error	Coni Cheesman (b) (4)	04 Sep 2020 23:52:50
User entered empty.	Coni Cheesman (b) (4)	

US3862044

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:19
User entered empty.	(b) (4) Coni Cheesman (b) (4)	04 Sep 2020 23:52:50

US3862044

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'Yes (Y)'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:39:48

US3862044

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User entered '1'	System	14 Sep 2020 21:39:48

US3862044

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:19
User entered 'Yes (Y)'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:40:15

US3862044

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:20

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:19
User entered '11 Sep 2020'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:40:15

US3862044

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:40:15

US3862044

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:19
User entered empty.	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:40:15

US3862044

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:19
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	18 Sep 2020 15:55:00

US3862044

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User entered '1'	System	18 Sep 2020 15:55:00

US3862044

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:38:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	18 Sep 2020 15:55:22

US3862044

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered '18 Sep 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	18 Sep 2020 15:55:22

US3862044

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:38:20

[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 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered 'Clinic (Clinic)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	18 Sep 2020 15:55:22

US3862044

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:38:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered 'VISIT2'	System	18 Sep 2020 15:55:22

US3862044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User accepted default value 'Pre-Dose (PREDOSE)'	Coni Cheesman (b) (4)	18 Sep 2020 19:18:37

US3862044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered 'Yes (Y)'	(b) (4) Coni Cheesman (b) (4)	18 Sep 2020 19:18:37

US3862044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered '18 Sep 2020'	(b) (4) Coni Cheesman (b) (4)	18 Sep 2020 19:18:37

US3862044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered '09:06'	(b) (4) Coni Cheesman (b) (4)	18 Sep 2020 19:18:37

US3862044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered '18 Sep 2020 09:06'	System	18 Sep 2020 19:18:37

US3862044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	18 Sep 2020 19:33:41
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	18 Sep 2020 19:33:41
User entered '98.8' F reason for change: New Information	Coni Cheesman (b) (4)	18 Sep 2020 19:33:41
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Sep 2020 19:18:37
User entered empty.	Coni Cheesman (b) (4)	18 Sep 2020 19:18:37

US3862044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
	(b) (4)	
User entered 'Oral (Oral)' reason for change: New Information	Coni Cheesman (b) (4)	18 Sep 2020 19:33:41
User entered empty.	Coni Cheesman (b) (4)	18 Sep 2020 19:18:37

US3862044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered empty.	(b) (4) Coni Cheesman (b) (4)	18 Sep 2020 19:18:37

US3862044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	18 Sep 2020 19:33:41
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	18 Sep 2020 19:33:41
User entered '67' reason for change: New Information	Coni Cheesman (b) (4)	18 Sep 2020 19:33:41
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Sep 2020 19:18:37
User entered empty.	Coni Cheesman (b) (4)	18 Sep 2020 19:18:37

US3862044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered 'bpm'	System	18 Sep 2020 19:33:41
User entered empty.	System	18 Sep 2020 19:18:37

US3862044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	18 Sep 2020 19:33:41
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	18 Sep 2020 19:33:41
User entered '16' reason for change: New Information	Coni Cheesman (b) (4)	18 Sep 2020 19:33:41
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Sep 2020 19:18:37
User entered empty.	Coni Cheesman (b) (4)	18 Sep 2020 19:18:37

US3862044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered 'breaths/min'	System	18 Sep 2020 19:33:41
User entered empty.	System	18 Sep 2020 19:18:37

US3862044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	18 Sep 2020 19:33:41
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	18 Sep 2020 19:33:41
User entered '139' reason for change: New Information	Coni Cheesman (b) (4)	18 Sep 2020 19:33:41
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Sep 2020 19:18:37
User entered empty.	Coni Cheesman (b) (4)	18 Sep 2020 19:18:37

US3862044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered 'mmHg'	System	18 Sep 2020 19:33:41
User entered empty.	System	18 Sep 2020 19:18:37

US3862044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	18 Sep 2020 19:33:41
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	18 Sep 2020 19:33:41
User entered '076' reason for change: New Information	Coni Cheesman (b) (4)	18 Sep 2020 19:33:41
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Sep 2020 19:18:37
User entered empty.	Coni Cheesman (b) (4)	18 Sep 2020 19:18:37

US3862044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered 'mmHg'	System	18 Sep 2020 19:33:41
User entered empty.	System	18 Sep 2020 19:18:37

US3862044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User accepted default value 'Post-Dose (POSTDOSE)'	Coni Cheesman (b) (4)	18 Sep 2020 19:18:37

US3862044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User closed query 'Per CDM: As per Section 8.2.5 of Protocol, on Day 1 and Day 29, vital sign measurements will be collected once before IP injection and at least 30 minutes after IP injection. Please confirm if the Post-dose VS assessments were performed. Else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:04:37
Query 'Per CDM: As per Section 8.2.5 of Protocol, on Day 1 and Day 29, vital sign measurements will be collected once before IP injection and at least 30 minutes after IP injection. Please confirm if the Post-dose VS assessments were performed. Else clarify.' answered with 'Discontinuation of treatment. Subject declined IP Injection. No VS needed to be assessed.' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 15:51:52
User opened query 'Per CDM: As per Section 8.2.5 of Protocol, on Day 1 and Day 29, vital sign measurements will be collected once before IP injection and at least 30 minutes after IP injection. Please confirm if the Post-dose VS assessments were performed. Else clarify.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 11:26:07
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 19:18:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 19:18:45
User entered 'No (N)' reason for change: Data Entry Error	Coni Cheesman (b) (4)	18 Sep 2020 19:18:45
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 19:18:37
User entered empty.	Coni Cheesman (b) (4)	18 Sep 2020 19:18:37

US3862044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered empty.	(b) (4) Coni Cheesman (b) (4)	18 Sep 2020 19:18:37

US3862044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered empty.	(b) (4) Coni Cheesman (b) (4)	18 Sep 2020 19:18:37

US3862044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered empty.	System	18 Sep 2020 19:18:37

US3862044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered empty.	(b) (4) Coni Cheesman (b) (4)	18 Sep 2020 19:18:37

US3862044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered empty.	(b) (4) Coni Cheesman (b) (4)	18 Sep 2020 19:18:37

US3862044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered empty.	(b) (4) Coni Cheesman (b) (4)	18 Sep 2020 19:18:37

US3862044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered empty.	(b) (4) Coni Cheesman (b) (4)	18 Sep 2020 19:18:37

US3862044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered empty.	System	18 Sep 2020 19:18:37

US3862044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered empty.	(b) (4) Coni Cheesman (b) (4)	18 Sep 2020 19:18:37

US3862044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered empty.	System	18 Sep 2020 19:18:37

US3862044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered empty.	(b) (4) Coni Cheesman (b) (4)	18 Sep 2020 19:18:37

US3862044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered empty.	System	18 Sep 2020 19:18:37

US3862044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered empty.	(b) (4) Coni Cheesman (b) (4)	18 Sep 2020 19:18:37

US3862044

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered empty.	System	18 Sep 2020 19:18:37

US3862044

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:38:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
	(b) (4)	
User entered 'No (N)'	Coni Cheesman (b) (4)	18 Sep 2020 19:19:12

US3862044

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:38:20

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered empty.	(b) (4) Coni Cheesman (b) (4)	18 Sep 2020 19:19:12

US3862044

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:38:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered 'No (N)'	(b) (4) Coni Cheesman (b) (4)	18 Sep 2020 19:19:33

US3862044

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:38:20

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User closed query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	(b) (4)	25 Sep 2020 20:19:19
User entered 'Participant declined due to Adverse Event (ADVERSE EVENT)' reason for change: Per Query Resolution	Chanei Henry (b) (4)	25 Sep 2020 20:19:19
Comment added 'Subject under evaluation for AE #01. Did not meet Inclusion Criterion #7'.	(b) (4)	18 Sep 2020 19:36:15
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	18 Sep 2020 19:19:33
User entered empty.	Coni Cheesman (b) (4)	18 Sep 2020 19:19:33

US3862044

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:38:20

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 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered empty.	(b) (4) Coni Cheesman (b) (4)	18 Sep 2020 19:19:33

US3862044

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:38:20

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered empty.	System	18 Sep 2020 19:19:33

US3862044

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered empty.	(b) (4) Coni Cheesman (b) (4)	18 Sep 2020 19:19:33

US3862044

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered empty.	(b) (4) Coni Cheesman (b) (4)	18 Sep 2020 19:19:33

US3862044

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered empty.	System	18 Sep 2020 19:19:33

US3862044

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered empty.	(b) (4) Coni Cheesman (b) (4)	18 Sep 2020 19:19:33

US3862044

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered empty.	System	18 Sep 2020 19:19:33

US3862044

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered empty.	System	18 Sep 2020 19:19:33

US3862044

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:38:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered 'Yes (Y)'	(b) (4) Coni Cheesman (b) (4)	18 Sep 2020 19:31:21

US3862044

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:38:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered '18 Sep 2020'	(b) (4) Coni Cheesman (b) (4)	18 Sep 2020 19:31:21

US3862044

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:38:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered '09:15'	(b) (4) Coni Cheesman (b) (4)	18 Sep 2020 19:31:21

US3862044

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered '18 Sep 2020 09:15'	System	18 Sep 2020 19:31:21

US3862044

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:38:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered '18 Sep 2020'	(b) (4) Coni Cheesman (b) (4)	18 Sep 2020 19:32:11

US3862044

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:38:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Coni Cheesman (b) (4)	18 Sep 2020 19:32:11

US3862044

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:38:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered 'No (N)'	(b) (4) Coni Cheesman (b) (4)	18 Sep 2020 19:32:11

US3862044

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:38:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered empty.	(b) (4) Coni Cheesman (b) (4)	18 Sep 2020 19:32:11

US3862044

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered empty.	System	18 Sep 2020 19:32:11

US3862044

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:38:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Coni Cheesman (b) (4)	18 Sep 2020 19:32:11

US3862044

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:38:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered 'Yes (Y)'	(b) (4) Coni Cheesman (b) (4)	18 Sep 2020 19:32:11

US3862044

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:38:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered '09:10'	(b) (4) Coni Cheesman (b) (4)	18 Sep 2020 19:32:11

US3862044

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered '18 Sep 2020 09:10'	System	18 Sep 2020 19:32:11

US3862044

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4) (b) (4)	25 Sep 2020 20:18:05

US3862044

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered '1'	System	25 Sep 2020 20:18:05

US3862044

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:19
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4) (b) (4)	28 Sep 2020 21:13:41

US3862044

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:19
User entered '28 Sep 2020'	(b) (4) Chanei Henry (b) (4) (b) (4)	28 Sep 2020 21:13:41

US3862044

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Chanei Henry (b) (4) (b) (4)	28 Sep 2020 21:13:41

US3862044

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:19
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	28 Sep 2020 21:13:41

US3862044

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:19
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4) (b) (4)	28 Sep 2020 21:13:45

US3862044

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered '1'	System	28 Sep 2020 21:13:45

US3862044

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:19
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4) (b) (4)	10 Oct 2020 00:18:08

US3862044

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:20

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:19
	(b) (4)	
User entered '2 Oct 2020' reason for change: Data Entry Error	Chanei Henry (b) (4)	10 Oct 2020 00:18:25
	(b) (4)	
User entered '9 Oct 2020'	Chanei Henry (b) (4)	10 Oct 2020 00:18:08
	(b) (4)	

US3862044

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Chanei Henry (b) (4) (b) (4)	10 Oct 2020 00:18:08

US3862044

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:19
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	10 Oct 2020 00:18:08

US3862044

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:19
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4) (b) (4)	10 Oct 2020 00:18:29

US3862044

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered '1'	System	10 Oct 2020 00:18:29

US3862044

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:19
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4) (b) (4)	10 Oct 2020 00:18:45

US3862044

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:19
User entered '9 Oct 2020'	(b) (4) Chanei Henry (b) (4) (b) (4)	10 Oct 2020 00:18:45

US3862044

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Chanei Henry (b) (4) (b) (4)	10 Oct 2020 00:18:45

US3862044

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:19
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	10 Oct 2020 00:18:45

US3862044

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:19
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4) (b) (4)	10 Oct 2020 00:18:50

US3862044

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered '1'	System	10 Oct 2020 00:18:50

US3862044

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:38:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:39
User entered 'Yes (Y)'	(b) (4) Shetel Anassi (b) (4) (b) (4)	19 Oct 2020 15:31:22

US3862044

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:39
User entered '16 Oct 2020'	(b) (4) Shetel Anassi (b) (4) (b) (4)	19 Oct 2020 15:31:22

US3862044

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:38:20

[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 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:39
User entered 'Clinic (Clinic)'	(b) (4) Shetel Anassi (b) (4) (b) (4)	19 Oct 2020 15:31:22

US3862044

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:38:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered 'VISIT3'	System	19 Oct 2020 15:31:22

US3862044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:39
User entered 'Yes (Y)'	(b) (4) Shetel Anassi (b) (4) (b) (4)	19 Oct 2020 15:32:02

US3862044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:39
User entered '16 Oct 2020'	(b) (4) Shetel Anassi (b) (4) (b) (4)	19 Oct 2020 15:32:02

US3862044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:39
User entered '15:55'	(b) (4) Shetel Anassi (b) (4) (b) (4)	19 Oct 2020 15:32:02

US3862044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered '16 Oct 2020 15:55'	System	19 Oct 2020 15:32:02

US3862044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:39
User entered '097.8' F	(b) (4) Shetel Anassi (b) (4) (b) (4)	19 Oct 2020 15:32:02

US3862044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:39
User entered 'Other (Other)'	(b) (4) Shetel Anassi (b) (4) (b) (4)	19 Oct 2020 15:32:02

US3862044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:39
User entered 'Temporal'	(b) (4) Shetel Anassi (b) (4) (b) (4)	19 Oct 2020 15:32:02

US3862044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:39
User entered '060'	(b) (4) Shetel Anassi (b) (4) (b) (4)	19 Oct 2020 15:32:02

US3862044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered 'bpm'	System	19 Oct 2020 15:32:02

US3862044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:39
User entered '016'	(b) (4) Shetel Anassi (b) (4) (b) (4)	19 Oct 2020 15:32:02

US3862044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered 'breaths/min'	System	19 Oct 2020 15:32:02

US3862044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:39
User entered '137'	(b) (4) Shetel Anassi (b) (4) (b) (4)	19 Oct 2020 15:32:02

US3862044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered 'mmHg'	System	19 Oct 2020 15:32:02

US3862044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:39
User entered '079'	(b) (4) Shetel Anassi (b) (4) (b) (4)	19 Oct 2020 15:32:02

US3862044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered 'mmHg'	System	19 Oct 2020 15:32:02

US3862044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 21:52:37

US3862044

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:20

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37

US3862044

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:38:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
	(b) (4)	
User entered 'No (N)'	Shetel Anassi (b) (4)	19 Oct 2020 15:32:32
	(b) (4)	

US3862044

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:38:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered empty.	(b) (4) Shetel Anassi (b) (4) (b) (4)	19 Oct 2020 15:32:32

US3862044

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:38:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered 'Yes (Y)'	(b) (4) Shetel Anassi (b) (4) (b) (4)	19 Oct 2020 15:33:22

US3862044

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:38:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered '16 Oct 2020'	(b) (4) Shetel Anassi (b) (4) (b) (4)	19 Oct 2020 15:33:22

US3862044

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:38:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered '16:15'	(b) (4) Shetel Anassi (b) (4) (b) (4)	19 Oct 2020 15:33:22

US3862044

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered '16 Oct 2020 16:15'	System	19 Oct 2020 15:33:22

US3862044

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:37
User entered 'Yes (Y)'	(b) (4) Shetel Anassi (b) (4) (b) (4)	19 Oct 2020 15:33:29

US3862044

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered '1'	System	19 Oct 2020 15:33:29

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
Data entry locked.	System	21 Aug 2020 15:29:34
User entered 'Day 64'	System	21 Aug 2020 15:29:34

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[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)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-10-21T06:03:35', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'dd491806-4f20-4d0c-ad19-459075b93284'	System	21 Oct 2020 11:04:18
User entered 'No (N)'	System	21 Oct 2020 11:04:18

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

Have you been exposed to someone with 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)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-10-21T06:04:02', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'dd491806-4f20-4d0c-ad19-459075b93284'	System	21 Oct 2020 11:04:18
User entered 'No (N)'	System	21 Oct 2020 11:04:18

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-10-21T06:04:15', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'dd491806-4f20-4d0c-ad19-459075b93284' User entered '21 Oct 2020 06:04:15'	System	21 Oct 2020 11:04:18
	System	21 Oct 2020 11:04:18

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
Data entry locked.	System	21 Aug 2020 15:29:34
User entered '21 Oct 2020 00:01'	System	21 Aug 2020 15:29:34

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
Data entry locked.	System	21 Aug 2020 15:29:34
User entered '25 Oct 2020 23:59'	System	21 Aug 2020 15:29:34

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
Data entry locked.	System	21 Aug 2020 15:29:34
User entered 'Day 71'	System	21 Aug 2020 15:29:34

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[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)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-10-31T18:55:14', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'f685668b-8028-4b1b-afd2-499bcef2fee5' User entered 'No (N)'	System	31 Oct 2020 23:55:28
	System	31 Oct 2020 23:55:28

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

Have you been exposed to someone with 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)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-10-31T18:55:19', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'f685668b-8028-4b1b-afd2-499bcef2fee5' User entered 'No (N)'	System	31 Oct 2020 23:55:28
	System	31 Oct 2020 23:55:28

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-10-31T18:55:24', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'f685668b-8028-4b1b-afd2-499bcef2fee5' User entered '31 Oct 2020 18:55:24'	System	31 Oct 2020 23:55:28
	System	31 Oct 2020 23:55:28

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
Data entry locked.	System	21 Aug 2020 15:29:34
User entered '28 Oct 2020 00:01'	System	21 Aug 2020 15:29:34

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
Data entry locked.	System	21 Aug 2020 15:29:34
User entered '01 Nov 2020 23:59'	System	21 Aug 2020 15:29:34

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
Data entry locked.	System	21 Aug 2020 15:29:34
User entered 'Day 78'	System	21 Aug 2020 15:29:34

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[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)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-11-06T12:00:19', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'd516be0d-e19c-4df4-abde-078447483ed6' User entered 'No (N)'	System	06 Nov 2020 18:00:46
	System	06 Nov 2020 18:00:46

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

Have you been exposed to someone with 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)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-11-06T12:00:25', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'd516be0d-e19c-4df4-abde-078447483ed6'	System	06 Nov 2020 18:00:46
User entered 'No (N)'	System	06 Nov 2020 18:00:46

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-11-06T12:00:28', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'd516be0d-e19c-4df4-abde-078447483ed6' User entered '06 Nov 2020 12:00:28'	System	06 Nov 2020 18:00:46
	System	06 Nov 2020 18:00:46

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
Data entry locked.	System	21 Aug 2020 15:29:34
User entered '04 Nov 2020 00:01'	System	21 Aug 2020 15:29:34

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:00:53
Data entry locked.	System	21 Aug 2020 15:29:34
User entered '08 Nov 2020 23:59'	System	21 Aug 2020 15:29:34

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:31:43
Data entry locked.	System	21 Aug 2020 15:29:34
User entered 'Day 92'	System	21 Aug 2020 15:29:34

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[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)	26 Apr 2021 21:52:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:31:43

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Have you been exposed to someone with 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)	26 Apr 2021 21:52:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:31:43

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Please 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)	26 Apr 2021 21:52:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:31:43

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[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)	26 Apr 2021 21:52:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:31:43

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:31:43

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:31:43

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:31:43

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:31:43

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:31:43

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:31:43

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:31:43

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:31:43

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:31:43

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:31:43

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:31:43

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:31:43

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:31:43

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:31:43

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:31:43

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:31:43

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:31:43

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Please 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)	26 Apr 2021 21:52:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:31:43

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[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)	26 Apr 2021 21:52:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:31:43

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Please 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)	26 Apr 2021 21:52:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:31:43

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:31:43

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:31:43
Data entry locked.	System	21 Aug 2020 15:29:34
User entered '18 Nov 2020 00:01'	System	21 Aug 2020 15:29:34

US3862044

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:31:43
Data entry locked.	System	21 Aug 2020 15:29:34
User entered '22 Nov 2020 23:59'	System	21 Aug 2020 15:29:34

US3862044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:43
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:31:43

US3862044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[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)	26 Apr 2021 21:52:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-11-24T12:00:44', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '7800b23a-31a2-430d-a5a0-3b39b10a17df' User entered 'No (N)'	System	24 Nov 2020 18:01:16
	System	24 Nov 2020 18:01:16

US3862044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

Have you been exposed to someone with 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)	26 Apr 2021 21:52:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-11-24T12:00:50', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '7800b23a-31a2-430d-a5a0-3b39b10a17df'	System	24 Nov 2020 18:01:16
User entered 'No (N)'	System	24 Nov 2020 18:01:16

US3862044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-11-24T12:00:55', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '7800b23a-31a2-430d-a5a0-3b39b10a17df' User entered '24 Nov 2020 12:00:55'	System	24 Nov 2020 18:01:16
	System	24 Nov 2020 18:01:16

US3862044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:43
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 00:31:43

US3862044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:43
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 00:31:43

US3862044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:43
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:31:43

US3862044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[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)	26 Apr 2021 21:52:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-11-29T00:02:40', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'e6a2c60e-27f5-4d65-9f11-0ceac4acb100'	System	29 Nov 2020 06:02:56
User entered 'No (N)'	System	29 Nov 2020 06:02:56

US3862044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

Have you been exposed to someone with 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)	26 Apr 2021 21:52:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-11-29T00:02:47', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'e6a2c60e-27f5-4d65-9f11-0ceac4acb100'	System	29 Nov 2020 06:02:56
User entered 'No (N)'	System	29 Nov 2020 06:02:56

US3862044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-11-29T00:02:53', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: 'e6a2c60e-27f5-4d65-9f11-0ceac4acb100' User entered '29 Nov 2020 00:02:53'	System	29 Nov 2020 06:02:56
	System	29 Nov 2020 06:02:56

US3862044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:43
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 00:31:43

US3862044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:43
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 00:31:43

US3862044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:43
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:31:43

US3862044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[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)	26 Apr 2021 21:52:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-12-08T12:01:49', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '4824a82c-9e39-4f24-888a-cdab3354879c' User entered 'No (N)'	System	08 Dec 2020 18:02:00
	System	08 Dec 2020 18:02:00

US3862044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

Have you been exposed to someone with 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)	26 Apr 2021 21:52:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-12-08T12:01:53', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '4824a82c-9e39-4f24-888a-cdab3354879c' User entered 'No (N)'	System	08 Dec 2020 18:02:00
	System	08 Dec 2020 18:02:00

US3862044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-12-08T12:01:56', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '4824a82c-9e39-4f24-888a-cdab3354879c' User entered '08 Dec 2020 12:01:56'	System	08 Dec 2020 18:02:00
	System	08 Dec 2020 18:02:00

US3862044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:43
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 00:31:43

US3862044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:43
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 00:31:43

US3862044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:43
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:31:43

US3862044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[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)	26 Apr 2021 21:52:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-12-13T05:44:44', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '864194b7-45c4-407c-a3fc-32b0987837c4' User entered 'No (N)'	System	13 Dec 2020 11:45:13
	System	13 Dec 2020 11:45:13

US3862044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

Have you been exposed to someone with 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)	26 Apr 2021 21:52:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-12-13T05:45:05', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '864194b7-45c4-407c-a3fc-32b0987837c4' User entered 'No (N)'	System	13 Dec 2020 11:45:13
	System	13 Dec 2020 11:45:13

US3862044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86772E1C-7EE7-4307-B15B-6FBDB7BBAC6A)', Time: '2020-12-13T05:45:11', User OID: 'PatientReportedOutcome (US3862044)', ODM File OID: '864194b7-45c4-407c-a3fc-32b0987837c4' User entered '13 Dec 2020 05:45:11'	System	13 Dec 2020 11:45:13
	System	13 Dec 2020 11:45:13

US3862044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:43
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 00:31:43

US3862044

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:43
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 00:31:43

US3862044

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4) (b) (4)	14 Nov 2020 01:32:44

US3862044

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered '13 Nov 2020'	(b) (4) Chanei Henry (b) (4) (b) (4)	14 Nov 2020 01:32:44

US3862044

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Chanei Henry (b) (4) (b) (4)	14 Nov 2020 01:32:44

US3862044

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	14 Nov 2020 01:32:44

US3862044

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:24
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4) (b) (4)	14 Nov 2020 01:32:50

US3862044

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:37
User entered '1'	System	14 Nov 2020 01:32:50

US3862044

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	14 Dec 2020 23:10:07

US3862044

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered '14 Dec 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	14 Dec 2020 23:10:07

US3862044

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	14 Dec 2020 23:10:07

US3862044

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	14 Dec 2020 23:10:07

US3862044

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'No (N)' reason for change: New Information	(b) (4) Sandra Francisco (b) (4)	16 Dec 2020 20:09:56
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4)	14 Dec 2020 23:10:10
	(b) (4)	

US3862044

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User entered empty.	System	16 Dec 2020 20:09:56
User entered '1'	System	14 Dec 2020 23:10:10

US3862044

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

Form: Visit Date

Generated On: 12 Aug 2021 13:38:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:08:32
User entered 'No (N)'	Carrie Kibler (b) (4)	30 Mar 2021 22:16:48
	(b) (4)	

US3862044

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

Form: Visit Date

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:08:32
User entered empty.	Carrie Kibler (b) (4)	30 Mar 2021 22:16:48

US3862044

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

Form: Visit Date

Generated On: 12 Aug 2021 13:38:20

[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 21:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:08:32
User entered empty.	Carrie Kibler (b) (4)	30 Mar 2021 22:16:48

US3862044

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

Form: Visit Date

Generated On: 12 Aug 2021 13:38:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User entered 'UNBLND_DECIDE'	System	30 Mar 2021 22:16:48

US3862044

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

Form: Unblinding

Generated On: 12 Aug 2021 13:38:20

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:08:32
User entered empty.	Thea Marie Cordero (b) (4)	29 Mar 2021 21:58:33

US3862044

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

Form: Unblinding

Generated On: 12 Aug 2021 13:38:20

[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 21:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:08:32
User entered '1'	Thea Marie Cordero (b) (4)	29 Mar 2021 21:58:33

US3862044

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

Form: Unblinding

Generated On: 12 Aug 2021 13:38:20

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:08:32
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	29 Mar 2021 21:58:33

US3862044

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

Form: Unblinding

Generated On: 12 Aug 2021 13:38:20

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:08:32
User entered 'Amendment 5 (Amendment 5)'	Thea Marie Cordero (b) (4)	29 Mar 2021 21:58:33

US3862044

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

Form: Unblinding

Generated On: 12 Aug 2021 13:38:20

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:08:32
User entered '15 Dec 2020'	Thea Marie Cordero (b) (4)	29 Mar 2021 21:58:33

US3862044

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

Form: Unblinding

Generated On: 12 Aug 2021 13:38:20

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:08:32
User entered 'Placebo (Placebo)'	Thea Marie Cordero (b) (4)	29 Mar 2021 21:58:33

US3862044

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

Form: Unblinding

Generated On: 12 Aug 2021 13:38:20

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:08:32
User entered 'Placebo (Placebo)'	Thea Marie Cordero (b) (4)	29 Mar 2021 21:58:33

US3862044

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

Form: Unblinding

Generated On: 12 Aug 2021 13:38:20

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:08:32
User entered 'Placebo (Placebo)'	Thea Marie Cordero (b) (4)	29 Mar 2021 21:58:33

US3862044

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

Form: Unblinding

Generated On: 12 Aug 2021 13:38:20

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:08:32
User entered 'No (N)'	Thea Marie Cordero (b) (4)	29 Mar 2021 21:58:33

US3862044

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

Form: Unblinding

Generated On: 12 Aug 2021 13:38:20

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User entered '1'	System	29 Mar 2021 21:58:33

US3862044

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

Form: Unblinding

Generated On: 12 Aug 2021 13:38:20

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User entered empty.	System	29 Mar 2021 21:58:33

US3862044

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:38:20

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'Yes (Y)'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:45:22

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 21:52:31

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:00
User coded data point as SOC: Investigations, HLT: Cardiac and vascular investigations (excl enzyme tests), HLT: Heart rate and pulse investigations, PT: Heart rate irregular, LLT: Heartbeats irregular - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	14 Sep 2020 21:47:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Sep 2020 21:47:52
Data point term sent to Coder	System	14 Sep 2020 21:46:56
User entered 'Irregular heart beat'	Coni Cheesman (b) (4)	14 Sep 2020 21:46:48

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:00
User entered 'Yes (Y)'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:46:48

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:00
User entered 'No (N)'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:46:48

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:00
User entered 'No (N)'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:46:48

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:00
User entered '10 Sep 2020'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:46:48

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:00
User entered empty.	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:46:48

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User entered empty.	System	14 Sep 2020 21:46:48

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:00
User entered 'No (N)'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:46:48

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:00
User entered '10 Sep 2020'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:46:48

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:00
User entered empty.	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:46:48

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User entered empty.	System	14 Sep 2020 21:46:48

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:00
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:46:48

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:00
User entered 'No (N)'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:46:48

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:00
User entered '0'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:46:48

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:00
User entered '0'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:46:48

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:00
User entered '0'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:46:48

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:00
User entered empty.	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:46:48

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:00
User entered empty.	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:46:48

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:00
User entered empty.	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:46:48

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:00
User entered empty.	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:46:48

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:00
User entered '0'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:46:48

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:00
User entered '0'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:46:48

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:00
User entered '0'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:46:48

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:00
User entered 'Not Related (NOT RELATED)'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:46:48

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:00
User entered 'Not Related (NOT RELATED)'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:46:48

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User closed query 'Per CDM Re-query: Please review V2D29 Exposure form. 'Was treatment given? = No. 'If No, reason' = Participant declined due to Adverse Event. Please consider updating this field to 'Investigational product withdrawn', else clarify.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Thea Marie Cordero (b) (4)	01 Apr 2021 12:48:55 29 Mar 2021 14:02:00
Query 'Per CDM Re-query: Please review V2D29 Exposure form. 'Was treatment given? = No. 'If No, reason' = Participant declined due to Adverse Event. Please consider updating this field to 'Investigational product withdrawn', else clarify.' answered with 'data entered in EDC and Source doc' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 23:49:53
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: New Information	(b) (4), (b) (6)	22 Mar 2021 23:49:34
User opened query 'Per CDM Re-query: Please review V2D29 Exposure form. 'Was treatment given? = No. 'If No, reason' = Participant declined due to Adverse Event. Please consider updating this field to 'Investigational product withdrawn', else clarify.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 16:15:51
User closed query 'Per CDM: If the primary reason for discontinuation from the treatment is reported as AE then the action taken with Investigational product should be marked as "Investigational product withdrawn" on AE CRF page. Kindly review and update the data as appropriate. Thank you!' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 16:15:51
Query 'Per CDM: If the primary reason for discontinuation from the treatment is reported as AE then the action taken with Investigational product should be marked as "Investigational product withdrawn" on AE CRF page. Kindly review and update the data as appropriate. Thank you!' answered with 'not reason to discontinue subject ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 18:45:33

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: If the primary reason for discontinuation from the treatment is reported as AE then the action taken with Investigational product should be marked as "Investigational product withdrawn" on AE CRF page. Kindly review and update the data as appropriate. Thank you!' (Site from DM).	(b) (4), (b) (6)	20 Dec 2020 05:21:24
User entered 'None (NONE)'	Coni Cheesman (b) (4)	14 Sep 2020 21:46:48

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:00
User entered '1'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:46:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:00
User entered '0'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:46:48

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:00
User entered '0'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:46:48

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:46:48

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:00
User entered empty.	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:46:48

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:00
User entered empty.	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:46:48

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User entered '0'	System	14 Sep 2020 21:46:48

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User entered '1'	System	14 Sep 2020 21:46:48

US3862044

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:20

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:38:20

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:50:03

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:38:20

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Aug 2020 15:53:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:53:17
Data point term sent to Coder	System	21 Aug 2020 15:52:33
User entered 'Pantoprazole'	Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:51:59

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:38:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
	(b) (4)	
User entered 'No (N)'	Sandra Francisco (b) (4)	21 Aug 2020 15:51:59
	(b) (4)	

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:38:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'GERD'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:51:59

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:38:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:01:51
Signature has been broken.	(b) (4)	18 Mar 2021 15:43:41
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered '20'	Sandra Francisco (b) (4)	21 Aug 2020 15:51:59

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:38:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
	(b) (4)	
User entered 'mg (mg)'	Sandra Francisco (b) (4)	21 Aug 2020 15:51:59
	(b) (4)	

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:38:20

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered empty.	(b) (4)	
	Sandra Francisco (b) (4)	21 Aug 2020 15:51:59
	(b) (4)	

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:38:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'as needed (PRN)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:51:59

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:38:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered empty.	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:51:59

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:38:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
	(b) (4)	
User entered 'Oral (ORAL)'	Sandra Francisco (b) (4)	21 Aug 2020 15:51:59
	(b) (4)	

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:38:20

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered empty.	(b) (4)	
	Sandra Francisco (b) (4)	21 Aug 2020 15:51:59
	(b) (4)	

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'un UNK 2019'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:51:59

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:38:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered '0'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:51:59

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:38:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
	(b) (4)	
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	21 Aug 2020 15:51:59
	(b) (4)	

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:38:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered empty.	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:51:59

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:38:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
	(b) (4)	
User entered 'No (N)'	Sandra Francisco (b) (4)	21 Aug 2020 15:51:59
	(b) (4)	

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:38:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User entered empty.	System	21 Aug 2020 15:51:59

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:38:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User entered empty.	System	21 Aug 2020 15:51:59

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:38:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User entered empty.	System	21 Aug 2020 15:51:59

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:38:20

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Aug 2020 16:00:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 16:00:28
Data point term sent to Coder	System	21 Aug 2020 15:59:47
User entered 'Vitamin C'	Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:58:56

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:38:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
	(b) (4)	
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	21 Aug 2020 15:58:56
	(b) (4)	

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:38:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'Vitamin supplement'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:58:56

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:38:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered '1'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:58:56

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:38:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User closed query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 20:03:22
Query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' answered with 'Data correct' (Site from DM).	Shetel Anassi (b) (4)	09 Nov 2020 21:31:21
User opened query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 03:58:39
User entered 'mg (mg)'	Sandra Francisco (b) (4)	21 Aug 2020 15:58:56

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:38:20

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered empty.	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:58:56

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:38:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
	(b) (4)	
User entered 'once daily (QD)'	Sandra Francisco (b) (4)	21 Aug 2020 15:58:56
	(b) (4)	

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:38:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered empty.	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:58:56

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:38:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
	(b) (4)	
User entered 'Oral (ORAL)'	Sandra Francisco (b) (4)	21 Aug 2020 15:58:56
	(b) (4)	

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:38:20

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered empty.	(b) (4)	
	Sandra Francisco (b) (4)	21 Aug 2020 15:58:56
	(b) (4)	

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:38:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'un UNK 2019'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:58:56

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:38:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered '0'	(b) (4) Sandra Francisco (b) (4) (b) (4)	21 Aug 2020 15:58:56

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:38:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
	(b) (4)	
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	21 Aug 2020 15:58:56
	(b) (4)	

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:38:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered empty.	(b) (4) Sandra Francisco (b) (4)	21 Aug 2020 15:58:56

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:38:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
	(b) (4)	
User entered 'No (N)'	Sandra Francisco (b) (4)	21 Aug 2020 15:58:56
	(b) (4)	

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:38:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User entered '1'	System	21 Aug 2020 15:58:56

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:38:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User entered '1'	System	21 Aug 2020 15:58:56

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:38:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User entered '804 (804)'	System	21 Aug 2020 15:58:56

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:38:20

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Aug 2020 17:22:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 17:22:45
Data point term sent to Coder	System	21 Aug 2020 17:22:12
User entered 'Vitamin D'	Chanei Henry (b) (4) (b) (4)	21 Aug 2020 17:21:32

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:38:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4) (b) (4)	21 Aug 2020 17:21:32

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:38:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'vitamin supplement'	(b) (4) Chanei Henry (b) (4) (b) (4)	21 Aug 2020 17:21:32

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:38:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered '1'	(b) (4) Chanei Henry (b) (4) (b) (4)	21 Aug 2020 17:21:32

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:38:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'tablet (TABLET)'	(b) (4) Chanei Henry (b) (4) (b) (4)	21 Aug 2020 17:21:32

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:38:20

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	21 Aug 2020 17:21:32

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:38:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
	(b) (4)	
User entered 'once daily (QD)'	Chanei Henry (b) (4)	21 Aug 2020 17:21:32
	(b) (4)	

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:38:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	21 Aug 2020 17:21:32

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:38:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'Oral (ORAL)'	(b) (4) Chanei Henry (b) (4) (b) (4)	21 Aug 2020 17:21:32

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:38:20

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	21 Aug 2020 17:21:32

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:38:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'UN UNK 2017'	(b) (4) Chanei Henry (b) (4) (b) (4)	21 Aug 2020 17:21:32

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:38:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered '0'	(b) (4) Chanei Henry (b) (4) (b) (4)	21 Aug 2020 17:21:32

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:38:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4) (b) (4)	21 Aug 2020 17:21:32

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:38:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	21 Aug 2020 17:21:32

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:38:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'No (N)'	(b) (4) Chanei Henry (b) (4) (b) (4)	21 Aug 2020 17:21:32

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:38:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User entered '1'	System	21 Aug 2020 17:21:32

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:38:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User entered '1'	System	21 Aug 2020 17:21:32

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:38:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User entered '804 (804)'	System	21 Aug 2020 17:21:32

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:38:20

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: VITAMIN E NOS, PRODUCTSYNONYM: VITAMIN E [VITAMIN E NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 17:24:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 17:24:18
Data point term sent to Coder	System	21 Aug 2020 17:23:15
User entered 'Vitamin E'	Chanei Henry (b) (4)	21 Aug 2020 17:22:41

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:38:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4) (b) (4)	21 Aug 2020 17:22:41

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:38:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'Vitamin supplement'	(b) (4) Chanei Henry (b) (4) (b) (4)	21 Aug 2020 17:22:41

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:38:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered '1'	(b) (4) Chanei Henry (b) (4) (b) (4)	21 Aug 2020 17:22:41

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:38:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'capsule (CAPSULE)'	(b) (4) Chanei Henry (b) (4) (b) (4)	21 Aug 2020 17:22:41

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:38:20

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	21 Aug 2020 17:22:41

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:38:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'once daily (QD)'	(b) (4) Chanei Henry (b) (4) (b) (4)	21 Aug 2020 17:22:41

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:38:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	21 Aug 2020 17:22:41

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:38:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'Oral (ORAL)'	(b) (4) Chanei Henry (b) (4) (b) (4)	21 Aug 2020 17:22:41

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:38:20

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	21 Aug 2020 17:22:41

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:38:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'un UNK 2017'	(b) (4) Chanei Henry (b) (4) (b) (4)	21 Aug 2020 17:22:41

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:38:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered '0'	(b) (4) Chanei Henry (b) (4) (b) (4)	21 Aug 2020 17:22:41

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:38:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4) (b) (4)	21 Aug 2020 17:22:41

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:38:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	21 Aug 2020 17:22:41

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:38:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'No (N)'	(b) (4) Chanei Henry (b) (4) (b) (4)	21 Aug 2020 17:22:41

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:38:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User entered '1'	System	21 Aug 2020 17:22:41

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:38:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User entered '1'	System	21 Aug 2020 17:22:41

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:38:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User entered '804 (804)'	System	21 Aug 2020 17:22:41

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:38:20

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Dec 2020 23:12:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Dec 2020 23:12:43
Data point term sent to Coder	System	14 Dec 2020 23:11:49
User entered 'influenza vaccine'	Carrie Kibler (b) (4)	14 Dec 2020 23:11:30

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:38:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	14 Dec 2020 23:11:30

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:38:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'influenza prevention'	(b) (4) Carrie Kibler (b) (4) (b) (4)	14 Dec 2020 23:11:30

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:38:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered '0.5'	(b) (4) Carrie Kibler (b) (4) (b) (4)	14 Dec 2020 23:11:30

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:38:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'mL (mL)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	14 Dec 2020 23:11:30

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:38:20

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	14 Dec 2020 23:11:30

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:38:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'once (ONCE)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	14 Dec 2020 23:11:30

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:38:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	14 Dec 2020 23:11:30

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:38:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	14 Dec 2020 23:11:30

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:38:20

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	14 Dec 2020 23:11:30

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:38:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered '10 Oct 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	14 Dec 2020 23:11:30

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:38:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	14 Dec 2020 23:11:30

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:38:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	14 Dec 2020 23:11:30

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:38:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered '10 Oct 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	14 Dec 2020 23:11:30

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:38:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	14 Dec 2020 23:11:30

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:38:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User entered empty.	System	14 Dec 2020 23:11:30

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:38:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User entered empty.	System	14 Dec 2020 23:11:30

US3862044

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:38:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User entered empty.	System	14 Dec 2020 23:11:30

US3862044

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 12 Aug 2021 13:38:20

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:02:00
User entered 'No (N)'	(b) (4), (b) (6)	23 Mar 2021 01:27:56

US3862044

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:38:20

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:01:51
User entered '18 Sep 2020'	(b) (4) Shetel Anassi (b) (4) (b) (4)	10 Dec 2020 18:18:02

US3862044

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:38:20

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:01:51
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 18:57:50
User entered 'Protocol deviation (specify) (PROTOCOL DEVIATION)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 18:51:29
User entered 'AE (specify) (ADVERSE EVENT)'	Shetel Anassi (b) (4)	10 Dec 2020 18:18:02
	(b) (4)	

US3862044

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:38:20

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)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:01:51
User closed query 'Per CDM: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then AE specify field must include '# symbol and 'AE logline number'. Please consider updating AE specify field to include only the '# symbol and 'AE logline number' (i.e. #1 for row 1). ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 16:07:37
User entered '#1' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 18:57:50
Query 'Per CDM: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then AE specify field must include '# symbol and 'AE logline number'. Please consider updating AE specify field to include only the '# symbol and 'AE logline number' (i.e. #1 for row 1). ' answered with 'data correction done ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 18:51:54
User entered 'EUA COVID19 vaccine received' reason for change: New Information	(b) (4), (b) (6)	16 Mar 2021 18:51:29
User opened query 'Per CDM: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then AE specify field must include '# symbol and 'AE logline number'. Please consider updating AE specify field to include only the '# symbol and 'AE logline number' (i.e. #1 for row 1). ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 14:52:24
Query 'Per CDM: Per sponsor review, please consider updating specify field to include AE, number sign, and number. (i.e. AE #1). Thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 14:52:10
User opened query 'Per CDM: Per sponsor review, please consider updating specify field to include AE, number sign, and number. (i.e. AE #1). Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:21:44
User entered 'AE 1'	Shetel Anassi (b) (4) (b) (4)	10 Dec 2020 18:18:02

US3862044

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:38:20

[Date of study discontinuation/completion \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered '15 Dec 2020'	(b) (4) Sandra Francisco (b) (4) (b) (4)	16 Dec 2020 20:15:22

US3862044

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:38:20

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'Other (OTHER)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	16 Dec 2020 20:15:22

US3862044

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:38:20

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)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered 'Request to unblind/EUA COVID-19 Vaccine'	(b) (4) Sandra Francisco (b) (4) (b) (4)	16 Dec 2020 20:15:22

US3862044

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:38:20

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered empty.	(b) (4)	16 Dec 2020 20:15:22
	Sandra Francisco (b) (4)	
	(b) (4)	

US3862044

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:38:20

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered empty.	(b) (4)	16 Dec 2020 20:15:22
	Sandra Francisco (b) (4)	
	(b) (4)	

US3862044

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:38:20

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered empty.	(b) (4) Sandra Francisco (b) (4) (b) (4)	16 Dec 2020 20:15:22

US3862044

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:38:20

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:52:31
User signature succeeded.	Thea Marie Cordero	12 Mar 2021 22:54:16
User entered empty.	(b) (4)	16 Dec 2020 20:15:22
	Sandra Francisco (b) (4)	
	(b) (4)	