

US3832043 (Prod: Keystone VitaLink Research - Anderson - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:00:22

All time stamps listed in this document are displayed in GMT

US3832043

Form: Participant Creation

Data signed: (b) (4) 21 Feb 2021 16:58:33

Generated On: 10 Jun 2021 10:00:22

[Participant ID](#)

US3832043

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

US3832043

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 14:00:55

Generated On: 10 Jun 2021 10:00:22

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

US3832043

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 14:00:55

Generated On: 10 Jun 2021 10:00:22

Date of Birth (MMM yyyy)	(b) (6) 1991
Age	29
Age Units	YEARS
Age (Derived)	29
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	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

US3832043

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 14:00:55

Generated On: 10 Jun 2021 10:00:22

Date of Informed Consent (<i>dd MMM yyyy</i>)	02 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify _____	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number _____	
Enrollment Trigger	1

US3832043

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 14:00:55

Generated On: 10 Jun 2021 10:00:22

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3832043

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 14:00:55

Generated On: 10 Jun 2021 10:00:22

Were any significant conditions reported?

Yes ☒

No ☐

US3832043

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 14:00:55

Generated On: 10 Jun 2021 10:00:22

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

US3832043

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 14:00:55

Generated On: 10 Jun 2021 10:00:22

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

US3832043

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 14:00:55

Generated On: 10 Jun 2021 10:00:22

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	02 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	13:20 (24 HR)
Vital Signs Date and Time (derived)	02 AUG 2020 13:20
Height (<i>xxx.x</i>)	65 in
Weight (<i>xxx.x</i>)	254 lb
BMI (<i>xxx.x</i>)	42.35619 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3832043

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 14:00:55

Generated On: 10 Jun 2021 10:00:22

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 AUG 2020

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

US3832043

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 14:00:55

Generated On: 10 Jun 2021 10:00:22

Date of assessment (dd MMM yyyy) 02 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

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

US3832043

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 14:00:55

Generated On: 10 Jun 2021 10:00:22

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	02 AUG 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3832043

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 14:00:55

Generated On: 10 Jun 2021 10:00:22

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

US3832043

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 14:00:55

Generated On: 10 Jun 2021 10:00:22

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	

US3832043

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 14:00:55

Generated On: 10 Jun 2021 10:00:22

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3832043

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 14:00:55

Generated On: 10 Jun 2021 10:00:22

What was the date of randomization? (dd MMM yyyy) 02 AUG 2020

What was the participant's randomization number? 142600

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 ☒

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 14:00:56

Generated On: 10 Jun 2021 10:00:22

Height	ND - Not Done
Weight	ND - Not Done

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 14:00:56

Generated On: 10 Jun 2021 10:00:22

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 AUG 2020
Time of assessment (00:00-23:59)	13:20 (24 HR)
Vital Signs Date and Time (derived)	02 AUG 2020 13:20
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 14:00:56

Generated On: 10 Jun 2021 10:00:22

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	02 AUG 2020
Time of assessment (00:00-23:59)	14:45 (24 HR)
Vital Signs Date and Time (derived)	02 AUG 2020 14:45
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3832043

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 14:00:55

Generated On: 10 Jun 2021 10:00:22

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.

US3832043

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 14:00:55

Generated On: 10 Jun 2021 10:00:22

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3832043

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 14:00:55

Generated On: 10 Jun 2021 10:00:22

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) 02 AUG 2020

What was the treatment time? (00:00-23:59) 14:12 (24 HR)

Treatment Date and Time (derived) 02 AUG 2020 14:12

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

US3832043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 14:00:55

Generated On: 10 Jun 2021 10:00:22

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	02 AUG 2020
Collection time (00:00-23:59)	13:48 (24 HR)
Collection date and time (derived)	02 AUG 2020 13:48

US3832043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 14:00:55

Generated On: 10 Jun 2021 10:00:22

Collection date (dd MMM yyyy)			02 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:47	02 AUG 2020 13:47
Nasopharyngeal Swab 2	No		

US3832043

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:00:55

Generated On: 10 Jun 2021 10:00:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 AUG 2020 14:47

PC Open Date & Time

02 AUG 2020 14:32

PC Close Date & Time

02 AUG 2020 17:02

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

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 97.6 °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	02 AUG 2020 22:29
PC Open Date & Time	02 AUG 2020 17:57
PC Close Date & Time	03 AUG 2020 11:59

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:22

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

97.6 °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

03 AUG 2020 21:38

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °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

05 AUG 2020 14:05

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:22

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

97.8 °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

06 AUG 2020 23:11

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:22

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 22:04

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:22

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 21:21

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 AUG 2020 14:48

PC Open Date & Time

02 AUG 2020 14:32

PC Close Date & Time

02 AUG 2020 17:02

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

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

02 AUG 2020 22:29

PC Open Date & Time

02 AUG 2020 17:57

PC Close Date & Time

03 AUG 2020 11:59

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:22

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

03 AUG 2020 21:39

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:22

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

05 AUG 2020 14:05

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:22

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

06 AUG 2020 23:11

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:22

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

07 AUG 2020 22:04

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:22

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

08 AUG 2020 21:21

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

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 ☐

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

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

No ☒

Yes ☐

PC Time stamp	02 AUG 2020 14:48
PC Open Date & Time	02 AUG 2020 14:32
PC Close Date & Time	02 AUG 2020 17:02

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

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 ☐

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

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

No ☒

Yes ☐

PC Time stamp	02 AUG 2020 22:30
PC Open Date & Time	02 AUG 2020 17:57
PC Close Date & Time	03 AUG 2020 11:59

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:22

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 ☒

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:22

Yes <input type="checkbox"/>	
PC Time stamp	03 AUG 2020 21:39
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:22

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
EAB) (1725)

48 of 2006

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:22

Yes ☐

PC Time stamp

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:22

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 ☒

PRODUCTION RELEASE (v12.003

50 of 2006

EAB) (1725)

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:22

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 14:05
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:22

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

52 of 2006

EAB) (1725)

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:22

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 23:12
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:22

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

54 of 2006

EAB) (1725)

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:22

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 22:04
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:22

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 ☒

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:22

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 21:22
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3832043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 14:00:55

Generated On: 10 Jun 2021 10:00:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832043

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:00:55

Generated On: 10 Jun 2021 10:00:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 16:58:33

Generated On: 10 Jun 2021 10:00:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832043

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 16:58:33

Generated On: 10 Jun 2021 10:00:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 16:58:33

Generated On: 10 Jun 2021 10:00:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832043

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 16:58:33

Generated On: 10 Jun 2021 10:00:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 14:00:56

Generated On: 10 Jun 2021 10:00:22

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3832043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 14:00:56

Generated On: 10 Jun 2021 10:00:22

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 SEP 2020
Time of assessment (00:00-23:59)	13:34 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 13:34
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3832043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 14:00:56

Generated On: 10 Jun 2021 10:00:22

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	4 SEP 2020
Time of assessment (00:00-23:59)	14:45 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 14:45
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3832043

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 14:00:56

Generated On: 10 Jun 2021 10:00:22

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 SEP 2020

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

US3832043

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 14:00:56

Generated On: 10 Jun 2021 10:00:22

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	4 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3832043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 14:00:56

Generated On: 10 Jun 2021 10:00:22

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) 4 SEP 2020

What was the treatment time? (00:00-23:59) 14:13 (24 HR)

Treatment Date and Time (derived) 4 SEP 2020 14:13

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

US3832043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 14:00:56

Generated On: 10 Jun 2021 10:00:22

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 SEP 2020
Collection time (00:00-23:59)	14:11 (24 HR)
Collection date and time (derived)	4 SEP 2020 14:11

US3832043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 14:00:56

Generated On: 10 Jun 2021 10:00:22

Collection date (dd MMM yyyy)			4 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:10	4 SEP 2020 14:10
Nasopharyngeal Swab 2	No		

US3832043

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:00:56

Generated On: 10 Jun 2021 10:00:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 14:48

PC Open Date & Time

04 SEP 2020 14:33

PC Close Date & Time

04 SEP 2020 17:03

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

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	04 SEP 2020 22:01
PC Open Date & Time	04 SEP 2020 17:58
PC Close Date & Time	05 SEP 2020 11:59

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:22

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

101.2 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

05 SEP 2020 21:35

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:22

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

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 22:30

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 00:01

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:22

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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 23:59

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 00:59

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:22

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

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 23:07

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 14:48

PC Open Date & Time

04 SEP 2020 14:33

PC Close Date & Time

04 SEP 2020 17:03

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

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

04 SEP 2020 22:00

PC Open Date & Time

04 SEP 2020 17:58

PC Close Date & Time

05 SEP 2020 11:59

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:22

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 ☐

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

105

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

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

Yes ☒

No ☐

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

105

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 21:38

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

72

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

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

Yes ☒

No ☐

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

72

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 22:30

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:22

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

08 SEP 2020 00:01

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:22

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

08 SEP 2020 23:59

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:22

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

10 SEP 2020 00:58

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:22

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

10 SEP 2020 23:07

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

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 ☐

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 14:49
---------------	-------------------

PC Open Date & Time	04 SEP 2020 14:33
---------------------	-------------------

PC Close Date & Time	04 SEP 2020 17:03
----------------------	-------------------

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

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 ☐

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 21:59
PC Open Date & Time	04 SEP 2020 17:58
PC Close Date & Time	05 SEP 2020 11:59

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:22

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 ☒

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:22

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 21:39
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:22

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 ☒

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:22

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 22:29
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:22

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 ☒

PRODUCTION RELEASE (v12.003

97 of 2006

EAB) (1725)

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:22

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 00:02
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:22

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

99 of 2006

EAB) (1725)

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:22

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 00:00
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:22

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

101 of 2006

EAB) (1725)

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:22

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 00:58
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:22

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 ☒

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:22

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 23:07
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3832043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 16:58:33

Generated On: 10 Jun 2021 10:00:22

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

US3832043

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 16:58:33

Generated On: 10 Jun 2021 10:00:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 14:00:55

Generated On: 10 Jun 2021 10:00:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832043

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:00:55

Generated On: 10 Jun 2021 10:00:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 14:00:55

Generated On: 10 Jun 2021 10:00:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832043

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:00:55

Generated On: 10 Jun 2021 10:00:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 14:00:56

Generated On: 10 Jun 2021 10:00:22

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3832043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 14:00:56

Generated On: 10 Jun 2021 10:00:22

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	2 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	10:18 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 10:18
Temperature (<i>xxx.x</i>)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	93 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3832043

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 14:00:56

Generated On: 10 Jun 2021 10:00:22

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 OCT 2020

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

US3832043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 14:00:56

Generated On: 10 Jun 2021 10:00:22

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

2 OCT 2020

Collection time (00:00-23:59)

10:31 (24 HR)

Collection date and time (derived)

2 OCT 2020 10:31

US3832043

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:00:56

Generated On: 10 Jun 2021 10:00:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

06 OCT 2020 12:07:11

Patient Cloud Open Date & Time

02 OCT 2020 00:01

Patient Cloud Close Date & Time

06 OCT 2020 23:59

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

11 OCT 2020 16:39:57

Patient Cloud Open Date & Time

09 OCT 2020 00:01

Patient Cloud Close Date & Time

13 OCT 2020 23:59

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

19 OCT 2020 09:37:19

Patient Cloud Open Date & Time

16 OCT 2020 00:01

Patient Cloud Close Date & Time

20 OCT 2020 23:59

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

Patient Cloud Open Date & Time

30 OCT 2020 00:01

Patient Cloud Close Date & Time

03 NOV 2020 23:59

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

Patient Cloud Open Date & Time

06 NOV 2020 00:01

Patient Cloud Close Date & Time

10 NOV 2020 23:59

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

Patient Cloud Open Date & Time

13 NOV 2020 00:01

Patient Cloud Close Date & Time

17 NOV 2020 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2020 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2020 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 DEC 2020 23:34:48

Patient Cloud Open Date & Time

01 DEC 2020 00:01

Patient Cloud Close Date & Time

05 DEC 2020 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 DEC 2020 11:02:24

Patient Cloud Open Date & Time

08 DEC 2020 00:01

Patient Cloud Close Date & Time

12 DEC 2020 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 DEC 2020 09:22:20

Patient Cloud Open Date & Time

15 DEC 2020 00:01

Patient Cloud Close Date & Time

19 DEC 2020 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 DEC 2020 12:36:18

Patient Cloud Open Date & Time

22 DEC 2020 00:01

Patient Cloud Close Date & Time

26 DEC 2020 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 DEC 2020 16:29:54

Patient Cloud Open Date & Time

29 DEC 2020 00:01

Patient Cloud Close Date & Time

02 JAN 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 JAN 2021 12:32:05
Patient Cloud Open Date & Time	05 JAN 2021 00:01
Patient Cloud Close Date & Time	09 JAN 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 JAN 2021 21:10:46

Patient Cloud Open Date & Time

19 JAN 2021 00:01

Patient Cloud Close Date & Time

23 JAN 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 FEB 2021 13:50:47

Patient Cloud Open Date & Time

16 FEB 2021 00:01

Patient Cloud Close Date & Time

20 FEB 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 FEB 2021 02:17:29

Patient Cloud Open Date & Time

23 FEB 2021 00:01

Patient Cloud Close Date & Time

27 FEB 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 MAR 2021 11:20:47

Patient Cloud Open Date & Time

09 MAR 2021 00:01

Patient Cloud Close Date & Time

13 MAR 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 MAR 2021 15:02:13

Patient Cloud Open Date & Time

16 MAR 2021 00:01

Patient Cloud Close Date & Time

20 MAR 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 MAR 2021 09:12:31

Patient Cloud Open Date & Time

23 MAR 2021 00:01

Patient Cloud Close Date & Time

27 MAR 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 MAR 2021 22:44:35

Patient Cloud Open Date & Time

30 MAR 2021 00:01

Patient Cloud Close Date & Time

03 APR 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 APR 2021 20:13:01

Patient Cloud Open Date & Time

06 APR 2021 00:01

Patient Cloud Close Date & Time

10 APR 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 APR 2021 16:27:01

Patient Cloud Open Date & Time

20 APR 2021 00:01

Patient Cloud Close Date & Time

24 APR 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 20:46:23

Patient Cloud Open Date & Time

27 APR 2021 00:01

Patient Cloud Close Date & Time

01 MAY 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission	
Patient Cloud Open Date & Time	15 JUN 2021 00:01
Patient Cloud Close Date & Time	19 JUN 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission	
Patient Cloud Open Date & Time	06 JUL 2021 00:01
Patient Cloud Close Date & Time	10 JUL 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 362

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission	
Patient Cloud Open Date & Time	10 AUG 2021 00:01
Patient Cloud Close Date & Time	14 AUG 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

Patient Cloud Open Date & Time	05 OCT 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	09 OCT 2021 23:59
---	-------------------

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

16 OCT 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission	
Patient Cloud Open Date & Time	19 OCT 2021 00:01
Patient Cloud Close Date & Time	23 OCT 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

30 OCT 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

13 NOV 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

Patient Cloud Open Date & Time	16 NOV 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	20 NOV 2021 23:59
---	-------------------

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

27 NOV 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

04 DEC 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

11 DEC 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission	
Patient Cloud Open Date & Time	14 DEC 2021 00:01
Patient Cloud Close Date & Time	18 DEC 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 509

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

25 DEC 2021 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JAN 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JAN 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JAN 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JAN 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JAN 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 551

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

05 FEB 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

12 FEB 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

19 FEB 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

26 FEB 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAR 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAR 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 593
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAR 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAR 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 APR 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 614

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

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

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

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

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

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

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

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 APR 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 APR 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 APR 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission	
Patient Cloud Open Date & Time	26 APR 2022 00:01
Patient Cloud Close Date & Time	30 APR 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAY 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAY 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAY 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAY 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUN 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUN 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUL 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUL 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUL 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUL 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUL 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

06 AUG 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

13 AUG 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

20 AUG 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

27 AUG 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

10 SEP 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

17 SEP 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

24 SEP 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2022 23:59

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

08 OCT 2022 23:59

US3832043

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:00:22

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 10:05:17

US3832043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 16:58:33

Generated On: 10 Jun 2021 10:00:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832043

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 16:58:33

Generated On: 10 Jun 2021 10:00:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832043

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 16:58:33

Generated On: 10 Jun 2021 10:00:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832043

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 16:58:33

Generated On: 10 Jun 2021 10:00:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832043

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 16:58:33

Generated On: 10 Jun 2021 10:00:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832043

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 16:58:33

Generated On: 10 Jun 2021 10:00:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832043

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 16:58:33

Generated On: 10 Jun 2021 10:00:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832043

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 16:58:33

Generated On: 10 Jun 2021 10:00:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832043

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 23:01:31

Generated On: 10 Jun 2021 10:00:22

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3832043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 23:01:31

Generated On: 10 Jun 2021 10:00:22

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3832043

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 23:01:31

Generated On: 10 Jun 2021 10:00:22

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.

US3832043

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 23:01:31

Generated On: 10 Jun 2021 10:00:22

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

9 MAR 2021

Collection time (00:00-23:59)

13:30 (24 HR)

Collection date and time (derived)

9 MAR 2021 13:30

US3832043

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 23:01:31

Generated On: 10 Jun 2021 10:00:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832043

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 15 Apr 2021 22:12:07

Generated On: 10 Jun 2021 10:00:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832043

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 15 Apr 2021 22:12:07

Generated On: 10 Jun 2021 10:00:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832043

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 18:40:37

Generated On: 10 Jun 2021 10:00:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832043

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 18:40:37

Generated On: 10 Jun 2021 10:00:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832043

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832043

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:22

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3832043

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:00:22

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

US3832043

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 10:00:22

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3832043

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

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 16:58:33

Generated On: 10 Jun 2021 10:00:22

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

Visit date (dd MMM yyyy)	19 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
------------	---------------

US3832043

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 23:01:31

Generated On: 10 Jun 2021 10:00:22

Date of updated informed consent (*dd MMM yyyy*) 19 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

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*) 19 JAN 2021

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 _____
Continuing with mRNA-1273 _____

US3832043

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 16:58:33

Generated On: 10 Jun 2021 10:00:22

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 JAN 2021

Collection time (00:00-23:59)

14:05 (24 HR)

Collection date and time (derived)

19 JAN 2021 14:05

US3832043

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 21 Feb 2021 16:58:33

Generated On: 10 Jun 2021 10:00:22

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 JAN 2021
Collection time (00:00 - 23:59)	14:00
Collection Date and Time (derived)	19 JAN 2021 14:00

US3832043

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 21 Feb 2021 16:58:33

Generated On: 10 Jun 2021 10:00:22

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 02:18:45

Generated On: 10 Jun 2021 10:00:22

AEID	USA-US100-2020-MRNA-1273-P30 1000001
Adverse event	SUSPECTED TOXIC SHOCK SYNDROME
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	23 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	25 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	23 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	25 AUG 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	334 of 2006

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 02:18:45

Generated On: 10 Jun 2021 10:00:22

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 02:18:45

Generated On: 10 Jun 2021 10:00:22

UPON ARRIVAL AT DAY 29
VISIT, SUBJECT REPORTED
BEING ADMITTED TO
HOSPITAL FOR SUSPECTED
BACTERIAL INFECTION FROM
23AUG2020 - 25AUG2020.
SUBJET REPORTS PRESENTING
WITH ELEVATED HEART RATE,
FEVER AND MODERATE
ABDOMINAL PAIN. SUBJECT
STATES A CHEST X-RAY AND
CT SCAN OF THE ABDOMEN
WERE PERFORMED. BOTH
WERE INSIGNIFICANT PER
SUBJECT REPORT. SUBJECT
STATES SHE WAS ADMITTED
FOR OBSERVATION AND
REPORTED BEING TREATED
WITH IV ANTIBIOTICS DURING
ADMISSION. SHE REPORTS
BEING GIVEN A 5 DAY COURSE
OF AUGMENTIN UPON
DISCHARGE. BACTERIAL
CULTURES WERE NEGATIVE
FOR SEPSIS PER SUBJECT
REPORT. MEDICAL RECORDS
WERE REQUESTED AND WILL
UPDATE WHEN RECORDS
RECEIVED AND REVIEWED.
FOLLOW-UP #1: MEDICAL
RECORDS FROM
HOSPITALIZATION REVIEWED
AND DISCUSSED WITH
SUBJECT. SUBJECT PRESENTED
TO HOSPITAL WITH SYMPTOMS

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 02:18:45

Generated On: 10 Jun 2021 10:00:22

OF MALAISE, CHILLS, NAUSEA,
ABDOMINAL PAIN AND FEVER.

VITAL SIGNS ON ADMISSION
(23/AUG/2020): TEMP 100.3F;
PULSE 143; RESP. 18; BP 155/98;
SP02 97%. SUBJECT ADMITTED

DUE TO SUSPECTED TOXIC
SHOCK SYNDROME OR SEPSIS.
SUBJECT HAD ELEVATED WBC
(15.92 K/UL; REFERENCE 3.50 -
10.80 K/UL) AND LACTATE (2.39
MMOL/L; REFERENCE 0.40 - 2.00
MMOL/L) UPON ADMISSION.

CHEST X-RAY AND
ABDOMINAL CT SCAN WERE
PERFORMED WITH NO
SIGNIFICANT FINDINGS.

BLOOD AND URINE CULTURES
PERFORMED THROUGHOUT
ADMISSION WERE NEGATIVE.

SUBJECT TREATED WITH IV
VANCOMYCIN, ZOSYN AND
CLINDAMYCIN DURING
HOSPITALIZATION. SUBJECT

GIVEN IV PEPCID FOR GI
PROPHYLAXIS. SUBJECT
NOTED TO HAVE A URINARY
TRACT INFECTION AND WAS

PROVIDED COURSE OF
AUGMENTIN UPON

DISCHARGE. AVG. VITAL SIGNS
OVER LAST 24HRS OF

ADMISSION WERE: TEMP. 98.0F;
PULSE 79; RESP. 18; BP 125/74;
SP02 97%. SUBJECT NOTED TO

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 02:18:45

Generated On: 10 Jun 2021 10:00:22

BE IN STABLE CONDITION AND
FEELING WELL UPON
DISCHARGE FROM HOSPITAL,
AND HAS RECOVERED FROM
SUSPECTED TOXIC SHOCK
SYNDROME AND URINARY
TRACT INFECTION.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 02:18:45

Generated On: 10 Jun 2021 10:00:22

AEID

Adverse event

URINARY TRACT INFECTION

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)

23 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

30 AUG 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

PRODUCTION RELEASE (v12.003

339 of 2006

EAB) (1725)

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 02:18:45

Generated On: 10 Jun 2021 10:00:22

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

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 02:18:45

Generated On: 10 Jun 2021 10:00:22

AEID	
Adverse event	WORSENING OF SEASONAL ALLERGIES
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	14 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 02:18:45

Generated On: 10 Jun 2021 10:00:22

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

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Mar 2021 12:05:55

Generated On: 10 Jun 2021 10:00:22

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

Yes ☒

No ☐

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

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 02:18:45

Generated On: 10 Jun 2021 10:00:22

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication SUSPECTED TOXIC SHOCK SYNDROME

Dose per administration 50

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

If dose unit is Other, specify MG/ML

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

344 of 2006

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 02:18:45

Generated On: 10 Jun 2021 10:00:22

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 02:18:45

Generated On: 10 Jun 2021 10:00:22

Name of Medication AUGMENTIN

Prophylaxis Yes ☐
No ☒

Indication URINARY TRACT INFECTION

Dose per administration 875/125

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

346 of 2006

EAB) (1725)

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 02:18:45

Generated On: 10 Jun 2021 10:00:22

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 02:18:45

Generated On: 10 Jun 2021 10:00:22

Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication AR - HEADACHE, FEVER

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

348 of 2006

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 02:18:45

Generated On: 10 Jun 2021 10:00:22

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		5 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 5 SEP 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 02:18:45

Generated On: 10 Jun 2021 10:00:22

Name of Medication ZOSYN 3.375
(12.0 G PIPERACILLIN/1.5 G
TAZOBACTAM).

Prophylaxis Yes ☐
No ☒

Indication SUSPECTED TOXIC SHOCK
SYNDROME

Dose per administration 12.0/1.5

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

350 of 2006

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 02:18:45

Generated On: 10 Jun 2021 10:00:22

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	25 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 02:18:45

Generated On: 10 Jun 2021 10:00:22

Name of Medication CLINDAMYCIN

Prophylaxis Yes ☐
No ☒

Indication SUSPECTED TOXIC SHOCK SYNDROME

Dose per administration 900

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

352 of 2006

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 02:18:45

Generated On: 10 Jun 2021 10:00:22

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	23 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	25 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 02:18:45

Generated On: 10 Jun 2021 10:00:22

Name of Medication PEPCID

Prophylaxis Yes ☒
No ☐

Indication GASTROINTESTINAL
PROPHYLAXIS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

354 of 2006

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 02:18:45

Generated On: 10 Jun 2021 10:00:22

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	23 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	25 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 02:18:45

Generated On: 10 Jun 2021 10:00:22

Name of Medication ZYRTEC

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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)

356 of 2006

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 02:18:45

Generated On: 10 Jun 2021 10:00:22

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

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 02:18:45

Generated On: 10 Jun 2021 10:00:22

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication ADVERSE EVENT WORSENING
OF SEASONAL ALLERGIES

Dose per administration 90

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

358 of 2006

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 02:18:45

Generated On: 10 Jun 2021 10:00:22

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	14 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3832043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 21 Feb 2021 16:58:33

Generated On: 10 Jun 2021 10:00:22

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3832043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 21 Feb 2021 16:58:33

Generated On: 10 Jun 2021 10:00:22

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
23 AUG 2020	CHEST X-RAY	Adverse Event	
24 AUG 2020	ABDOMINAL CT SCAN	Adverse Event	

US3832043

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:00:22

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3832043

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:00:22

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 21 Feb 2021 16:58:33

Generated On: 10 Jun 2021 10:00:22

SAEID	USA-US100-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 21 Feb 2021 16:58:33

Generated On: 10 Jun 2021 10:00:22

SAEID	USA-US100-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	07/SEP/2020 15:54
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 21 Feb 2021 16:58:33

Generated On: 10 Jun 2021 10:00:22

SAEID	USA-US100-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	01/OCT/2020 16:59
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 21 Feb 2021 16:58:33

Generated On: 10 Jun 2021 10:00:22

SAEID	USA-US100-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	14/OCT/2020 16:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3832043 (Prod: Keystone VitaLink Research - Anderson - PPDS)

US3832043

Form: Participant Creation

Generated On: 10 Jun 2021 10:00:22

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered 'US3832043'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Aug 2020 16:59:07

US3832043

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:00:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:50:59
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 18:14:58

US3832043

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:52:06
User entered '02 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Aug 2020 16:59:08

US3832043

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:52:06
User entered 'Clinic (Clinic)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 18:14:58

US3832043

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:00:22

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:51
User entered 'SCRN'	System	02 Aug 2020 18:14:58

US3832043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:52:36
User entered (b) (6) 1991'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Aug 2020 16:59:09

US3832043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:22

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:52:36
User entered '29'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 18:15:16

US3832043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:22

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User entered 'YEARS'	System	02 Aug 2020 18:15:16

US3832043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:22

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User entered '29'	System	02 Aug 2020 18:15:43

US3832043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:22

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:52:36
User entered 'Female (F)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 18:15:16

US3832043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:22

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:52:36
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 18:15:16

US3832043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:22

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:52:36
User entered 'l'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 18:15:16

US3832043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:22

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:52:36
User entered '0'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 18:15:16

US3832043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:22

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:52:36
User entered '0'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 18:15:16

US3832043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:22

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:52:36
User entered '0'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 18:15:16

US3832043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:22

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:52:36
User entered '0'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 18:15:16

US3832043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:22

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:52:36
User entered '0'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 18:15:16

US3832043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:22

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:52:36
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Aug 2020 18:15:16

US3832043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:22

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:52:36
User entered '0'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 18:15:16

US3832043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:22

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:52:36
User entered '0'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 18:15:16

US3832043

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:22

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 20:35:53
User entered '02 Aug 2020'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 18:15:43

US3832043

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User entered 'Aug 2020'	System	02 Aug 2020 18:15:43

US3832043

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User entered '2020'	System	02 Aug 2020 18:15:43

US3832043

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:22

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 20:35:53
User entered 'Amendment 1 (1)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 18:15:43

US3832043

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 20:35:53
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 18:15:43

US3832043

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 20:35:53
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Aug 2020 18:15:43

US3832043

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:22

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 20:35:53
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Aug 2020 18:15:43

US3832043

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:22

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 20:35:53
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 18:15:43

US3832043

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:22

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 20:35:53
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	02 Aug 2020 16:59:08

US3832043

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:22

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User entered 'I'	System	02 Aug 2020 18:15:50

US3832043

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:52:50
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 18:15:50

US3832043

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:00:22

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Un-verified.	Emma Partin (b) (4)	28 Oct 2020 18:19:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Emma Partin (b) (4)	28 Oct 2020 18:19:08
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:53:17
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:12:28

US3832043

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:22

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User coded data point as SOC: Gastrointestinal disorders, HLGT: Dental and gingival conditions, HLT: Dental disorders NEC, PT: Tooth impacted, LLT: Impacted wisdom tooth - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 16:58:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 16:58:33
Data point term sent to Coder	System	11 Nov 2020 16:41:26
User closed query 'DM-Coding: please clarify this clinical event with more details and amend /update the term accordingly in the diagnosis field to enable coding. Is this Hyperaesthesia/ Injury / Pain and etc.' (Site from System).	System	11 Nov 2020 16:40:51
Query 'DM-Coding: please clarify this clinical event with more details and amend /update the term accordingly in the diagnosis field to enable coding. Is this Hyperaesthesia/ Injury / Pain and etc.' answered with 'Reviewed and updated per subject report' (Site from System).	Danyel Johnson (b) (4)	11 Nov 2020 16:40:51
User entered 'WISDOM TEETH Impaction' reason for change: Data Entry Error	Danyel Johnson (b) (4)	11 Nov 2020 16:40:44
User opened query 'DM-Coding: please clarify this clinical event with more details and amend /update the term accordingly in the diagnosis field to enable coding. Is this Hyperaesthesia/ Injury / Pain and etc.' (Site from System).	Coder Import (b) (4)	11 Nov 2020 08:08:47
Data point term sent to Coder	System	28 Oct 2020 18:21:46
User entered 'Wisdom Teeth Complication'	Emma Partin (b) (4)	28 Oct 2020 18:20:58

US3832043

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'un UNK 2014'	Emma Partin (b) (4)	28 Oct 2020 18:20:58

US3832043

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '0'	Emma Partin (b) (4)	28 Oct 2020 18:20:58

US3832043

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'No (N)'	Emma Partin (b) (4)	28 Oct 2020 18:20:58

US3832043

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'un UNK 2014'	Emma Partin (b) (4)	28 Oct 2020 18:20:58

US3832043

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '0'	Emma Partin (b) (4)	28 Oct 2020 18:20:58

US3832043

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User entered 'Jan 2014'	System	28 Oct 2020 18:20:58

US3832043

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User entered '2014'	System	28 Oct 2020 18:20:58

US3832043

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User entered 'Jan 2014'	System	28 Oct 2020 18:20:58

US3832043

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User entered '2014'	System	28 Oct 2020 18:20:58

US3832043

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:22

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Dental and gingival therapeutic procedures, PT: Wisdom teeth removal, LLT: Wisdom teeth removal - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:47:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:47:48
Data point term sent to Coder	System	28 Oct 2020 18:21:46
User entered 'Wisdom Teeth Removal'	Emma Partin (b) (4)	28 Oct 2020 18:21:37

US3832043

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'un UNK 2014'	Emma Partin (b) (4)	28 Oct 2020 18:21:37

US3832043

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '0'	Emma Partin (b) (4)	28 Oct 2020 18:21:37

US3832043

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'No (N)'	Emma Partin (b) (4)	28 Oct 2020 18:21:37

US3832043

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'un UNK 2014'	Emma Partin (b) (4)	28 Oct 2020 18:21:37

US3832043

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '0'	Emma Partin (b) (4)	28 Oct 2020 18:21:37

US3832043

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User entered 'Jan 2014'	System	28 Oct 2020 18:21:37

US3832043

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User entered '2014'	System	28 Oct 2020 18:21:37

US3832043

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User entered 'Jan 2014'	System	28 Oct 2020 18:21:37

US3832043

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User entered '2014'	System	28 Oct 2020 18:21:37

US3832043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:55:00
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:18:27

US3832043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:55:00
User entered '02 Aug 2020'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:18:27

US3832043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:55:00
User entered '13:20'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:18:27

US3832043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:51
User entered '02 Aug 2020 13:20'	System	02 Aug 2020 20:18:27

US3832043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:55:00
User entered '65' in	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:18:27
DataPoint set to visible.	System	02 Aug 2020 18:15:50

US3832043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:55:00
User entered '254' lb	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:18:27
DataPoint set to visible.	System	02 Aug 2020 18:15:50

US3832043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:51
Amendment Manager: User entered '42.35619'	System	16 Sep 2020 23:40:45
User entered '42.4'	System	02 Aug 2020 20:18:27
DataPoint set to visible.	System	02 Aug 2020 18:15:50

US3832043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:51
User entered 'kg/m2'	System	02 Aug 2020 20:18:27
DataPoint set to visible.	System	02 Aug 2020 18:15:50

US3832043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User closed query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:44:46
Query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.	Danyel Johnson (b) (4)	03 Nov 2020 16:43:43
' answered with 'Update per query ' (Site from CRA).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4)	03 Nov 2020 16:43:36
User opened query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:47:06
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 22:46:31
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:55:00
User entered '97.7' F	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:18:27
	(b) (4)	

US3832043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User closed query 'Please delete' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:44:50
Query 'Please delete' answered with 'Update per query ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 16:43:47
User entered empty; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 16:43:36
User opened query 'Please delete' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 22:47:20
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:55:00
User entered 'Oral (Oral)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Aug 2020 20:18:27

US3832043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 22:46:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:55:00
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:18:27

US3832043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User closed query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:44:54
Query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. ' answered with 'Update per query ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 16:43:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 16:43:36
User opened query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. ' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 22:48:05
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 22:47:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:55:00
User entered '87'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Aug 2020 20:18:27

US3832043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:51
User entered 'bpm'	System	02 Aug 2020 20:18:27

US3832043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User closed query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. ' (Site from CRA).	(b) (4)	
Query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.	(b) (4), (b) (6)	10 Nov 2020 19:44:57
' answered with 'Update per query ' (Site from CRA).		
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4)	03 Nov 2020 16:43:58
User opened query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. ' (Site from CRA).	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 16:43:36
DataPoint Verified.	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 23:02:32
DataPoint Verified.	(b) (4), (b) (6)	
User entered '16'	(b) (4), (b) (6)	02 Nov 2020 22:52:21
	(b) (4), (b) (6)	02 Nov 2020 22:48:07
	(b) (4), (b) (6)	02 Nov 2020 22:47:52
	(b) (4), (b) (6)	27 Oct 2020 16:55:00
	(b) (4), (b) (6)	
	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:18:27
	(b) (4)	

US3832043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:51
User entered 'breaths/min'	System	02 Aug 2020 20:18:27

US3832043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User closed query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.	(b) (4)	
' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:44:59
Query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.	Danyel Johnson (b) (4)	03 Nov 2020 16:44:03
' answered with 'Update per query ' (Site from CRA).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4)	03 Nov 2020 16:43:36
User opened query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.	(b) (4)	
' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 23:02:53
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 22:47:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:55:00
User entered '117'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:18:27
	(b) (4)	

US3832043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:51
User entered 'mmHg'	System	02 Aug 2020 20:18:27

US3832043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User closed query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:45:06
Query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.	Danyel Johnson (b) (4)	03 Nov 2020 16:44:08
' answered with 'Update per query ' (Site from CRA).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4)	03 Nov 2020 16:43:36
User opened query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	02 Nov 2020 23:03:16
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 22:47:54
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:55:00
User entered '84'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:18:27
	(b) (4)	

US3832043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:51
User entered 'mmHg'	System	02 Aug 2020 20:18:27

US3832043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:51

US3832043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:51

US3832043

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:55:10
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:18:39

US3832043

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:22

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:55:10
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 09:03:54
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		04 Sep 2020 17:21:04
User entered '02 Aug 2020'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:18:39
	(b) (4)	

US3832043

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:00:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:55:40
User entered '02 Aug 2020'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:19:13

US3832043

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:55:40
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:19:13

US3832043

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:00:22

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:55:40
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:19:13

US3832043

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:55:40
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:19:13

US3832043

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:55:40
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:19:13

US3832043

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:00:22

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:55:40
User entered '0'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:19:13

US3832043

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:55:40
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:19:13

US3832043

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:00:22

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:55:40
User entered '0'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:19:13

US3832043

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:00:22

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:02:07
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:19:40

US3832043

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:00:22

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:02:07
User entered '02 Aug 2020'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:19:40

US3832043

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:00:22

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:02:07
User entered 'Urine (URINE)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:19:40

US3832043

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:00:22

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:02:07
User entered 'Negative (NEGATIVE)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:19:40

US3832043

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:00:22

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:02:07
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:19:40

US3832043

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:00:22

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:02:07
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:19:40

US3832043

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:00:22

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:02:07
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:19:40

US3832043

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User entered empty.	System	02 Aug 2020 20:19:40

US3832043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:03:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:22:45

US3832043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:03:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:22:45

US3832043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:22

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)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:03:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:22:45

US3832043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:22

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)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:03:42
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:22:45

US3832043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:03:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:22:45

US3832043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:22

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)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:03:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:22:45

US3832043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:22

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)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:03:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:22:45

US3832043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:22

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)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:03:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:22:45

US3832043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:22

[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)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:03:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:22:45

US3832043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:22

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)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:03:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:22:45

US3832043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:22

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)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:03:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:22:45

US3832043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:22

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User closed query 'Per EDC guidelines, this section is for occupation only. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:01:52
Query 'Per EDC guidelines, this section is for occupation only. Please review and reconcile.' answered with 'updated accordingly ' (Site from CRA).	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:14:46
User entered 'No (N)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:14:31
User opened query 'Per EDC guidelines, this section is for occupation only. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:39:37
Query 'This section is for working conditions. please delete as it is captured on demographics' canceled (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 23:09:17
User opened query 'This section is for working conditions. please delete as it is captured on demographics' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 23:05:18
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 23:04:35
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:03:42
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:22:45

US3832043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:22

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User closed query 'Per EDC guidelines, this section is for occupation only. Please review and reconcile' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:01:56
Query 'Per EDC guidelines, this section is for occupation only. Please review and reconcile' answered with 'updated ' (Site from CRA).	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:14:52
DataPoint Un-verified.	(b) (4)	
	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:14:31
User entered empty; reason for change Data Entry Error	(b) (4)	
	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:14:31
User opened query 'Per EDC guidelines, this section is for occupation only. Please review and reconcile' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:39:57
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:03:42
User entered 'Has the participant attended any large group events in the past few weeks'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:22:45
	(b) (4)	

US3832043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:22

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User closed query 'Please select living condition. Please note, one of the options below needs to selected. If selecting "other", please specify (IE Homeless)' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:44:00
Query 'Please select living condition. Please note, one of the options below needs to selected. If selecting "other", please specify (IE Homeless)' answered with 'updated ' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	09 Nov 2020 16:09:00
User entered '0' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	09 Nov 2020 16:08:49
User opened query 'Please select living condition. Please note, one of the options below needs to selected. If selecting "other", please specify (IE Homeless)' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:02:09
User closed query "No Risk Identified" is not checked, however no other risks are selected. Please review and reconcile.' (Site from System).	System	03 Nov 2020 16:42:53
User entered '1' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 16:42:53
User opened query "No Risk Identified" is not checked, however no other risks are selected. Please review and reconcile.' (Site from System).	System	03 Nov 2020 16:42:33
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Aug 2020 20:22:45

US3832043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:22

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:03:42
User entered '0'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:22:45

US3832043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:22

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)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:03:42
User entered '0'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:22:45

US3832043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:22

[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)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:03:42
User entered '0'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:22:45

US3832043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:22

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)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:03:42
User entered '0'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:22:45

US3832043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4)	09 Nov 2020 16:08:49
User entered '1' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	09 Nov 2020 16:08:49
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:03:42
User entered '0'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:22:45

US3832043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:22

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User closed query 'Please delete' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:40:04
Query 'Please delete' answered with 'Update per query ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 16:42:42
User entered '0' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 16:42:33
User opened query 'Please delete' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 22:44:58
User entered '1'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Aug 2020 20:22:45

US3832043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:22

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:51
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User closed query 'This section is for living conditions. please delete.' (Site from CRA).	(b) (4)	
Query 'This section is for living conditions. please delete.' answered with 'Update per query ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:40:06
User entered empty; reason for change Data Entry Error	Danyel Johnson (b) (4)	03 Nov 2020 16:42:46
User opened query 'This section is for living conditions. please delete.' (Site from CRA).	(b) (4)	
DataPoint Un-verified.	Danyel Johnson (b) (4)	03 Nov 2020 16:42:33
DataPoint Verified.	(b) (4)	
User entered 'plan on routinely (e.g., weekly) going to places where people gather (e.g., places of worship, restaurants, bars, sporting events) over the coming months'	(b) (4), (b) (6)	02 Nov 2020 22:45:52
	(b) (4), (b) (6)	02 Nov 2020 22:45:42
	(b) (4), (b) (6)	27 Oct 2020 17:03:42
	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:22:45
	(b) (4)	

US3832043

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:00:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:03:54
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 18:16:13

US3832043

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:03:54
User entered '02 Aug 2020'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 18:16:13

US3832043

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:03:54
User entered 'Clinic (Clinic)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 18:16:13

US3832043

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:00:22

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'VISIT1'	System	02 Aug 2020 18:16:13

US3832043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:05:54
User entered '02 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Aug 2020 17:39:12

US3832043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:00:22

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:05:54
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:40:42
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:40:42
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Aug 2020 17:39:12
User entered '142600' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	02 Aug 2020 17:39:12

US3832043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:00:22

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:05:54
User closed query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	21 Oct 2020 16:57:54
Query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' answered by data change (Site from System).	System	21 Oct 2020 16:57:54
Amendment Manager: User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	30 Sep 2020 21:09:57
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	30 Sep 2020 21:09:57
User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	02 Aug 2020 20:25:02
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Aug 2020 17:39:12

US3832043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:00:22

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)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:05:54
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:25:02

US3832043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:00:22

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)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:05:54
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:25:02

US3832043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:05:54
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 16:57:54
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Aug 2020 20:25:02

US3832043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:05:54
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:25:02

US3832043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:00:22

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:05:54
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:25:02

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:22

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:35:23
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'Verified and updated' (Site from CRA).	Alyssa-Kay Peay (b) (4)	10 Nov 2020 20:58:18
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	10 Nov 2020 20:58:05
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:45:33
User closed query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:45:33
Query 'Per query response, ND. Please enter ND into the database.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4)	09 Nov 2020 16:09:11
User opened query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:58:46
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:58:46
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:15:23
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:15:19
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:15:19
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:40:45
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:07:10
User entered '65' in	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:22

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:35:25
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'Verified and updated' (Site from CRA).	Alyssa-Kay Peay (b) (4)	10 Nov 2020 20:58:26
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	10 Nov 2020 20:58:05
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:45:44
User closed query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:45:44
Query 'Per query response, ND. Please enter ND into the database.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4)	09 Nov 2020 16:09:17
User opened query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:58:56
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:58:56
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:15:25
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:15:19
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:15:19
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:40:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:07:10
User entered '254' lb	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:22

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:35:23
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'Verified and updated' (Site from CRA).	Alyssa-Kay Peay (b) (4)	10 Nov 2020 20:58:18
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	10 Nov 2020 20:58:05
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:45:33
User closed query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:45:33
Query 'Per query response, ND. Please enter ND into the database.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4)	09 Nov 2020 16:09:11
User opened query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:58:46
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:58:46
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:15:23
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:15:19
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:15:19
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:40:45
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:07:10
User entered '65' in	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:22

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:35:25
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'Verified and updated' (Site from CRA).	Alyssa-Kay Peay (b) (4)	10 Nov 2020 20:58:26
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	10 Nov 2020 20:58:05
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:45:44
User closed query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:45:44
Query 'Per query response, ND. Please enter ND into the database.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4)	09 Nov 2020 16:09:17
User opened query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:58:56
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:58:56
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:15:25
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:15:19
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:15:19
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:40:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:07:10
User entered '254' lb	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:22

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User accepted default value 'Pre-Dose (PREDOSE)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:07:10
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:07:10
User entered '02 Aug 2020'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:07:10
User entered '13:20'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered '02 Aug 2020 13:20'	System	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:07:10
User entered '97.7' F	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:07:10
User entered 'Oral (Oral)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:07:10
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:07:10
User entered '87'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'bpm'	System	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:07:10
User entered '16'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'breaths/min'	System	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:07:10
User entered '117'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'mmHg'	System	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:07:10
User entered '84'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'mmHg'	System	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:22

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:35:23
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'Verified and updated' (Site from CRA).	Alyssa-Kay Peay (b) (4)	10 Nov 2020 20:58:18
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	10 Nov 2020 20:58:05
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:45:33
User closed query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:45:33
Query 'Per query response, ND. Please enter ND into the database.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4)	09 Nov 2020 16:09:11
User opened query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:58:46
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:58:46
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:15:23
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:15:19
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:15:19
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:40:45
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:07:10
User entered '65' in	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:22

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:35:25
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'Verified and updated' (Site from CRA).	Alyssa-Kay Peay (b) (4)	10 Nov 2020 20:58:26
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	10 Nov 2020 20:58:05
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:45:44
User closed query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:45:44
Query 'Per query response, ND. Please enter ND into the database.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4)	09 Nov 2020 16:09:17
User opened query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:58:56
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:58:56
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:15:25
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:15:19
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:15:19
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:40:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:07:10
User entered '254' lb	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:22

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User accepted default value 'Post-Dose (POSTDOSE)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:07:10
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:07:10
User entered '02 Aug 2020'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:07:10
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	06 Aug 2020 15:25:14
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 min per protocol' (Site from System).	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:32:46
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		02 Aug 2020 20:32:31
User entered '14:45'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered '02 Aug 2020 14:45'	System	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:07:10
User entered '98.5' F	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:07:10
User entered 'Oral (Oral)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:07:10
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:07:10
User entered '84'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'bpm'	System	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:07:10
User entered '16'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'breaths/min'	System	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:07:10
User entered '119'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'mmHg'	System	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:07:10
User entered '81'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'mmHg'	System	02 Aug 2020 20:32:31

US3832043

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:22

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User closed query 'Per EDC guidelines, NO must be recorded if Day 0 and Day 1 are performed on the same date, this is only entered on Day . Please verify and reconcile ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 21:59:29
Query 'Per EDC guidelines, NO must be recorded if Day 0 and Day 1 are performed on the same date, this is only entered on Day . Please verify and reconcile ' answered with 'Updated per query ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	05 Nov 2020 18:16:06
DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	05 Nov 2020 18:16:01
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	05 Nov 2020 18:16:01
User opened query 'Per EDC guidelines, NO must be recorded if Day 0 and Day 1 are performed on the same date, this is only entered on Day . Please verify and reconcile ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:41:08
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:07:16
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Aug 2020 20:32:57

US3832043

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:22

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User closed query 'Per EDC guidelines, NO must be recorded if Day 0 and Day 1 are performed on the same date, this is only entered on Day . Please verify and reconcile ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 21:59:32
Query 'Per EDC guidelines, NO must be recorded if Day 0 and Day 1 are performed on the same date, this is only entered on Day . Please verify and reconcile ' answered with 'Updated per query ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	05 Nov 2020 18:16:10
DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	05 Nov 2020 18:16:01
User entered empty; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	05 Nov 2020 18:16:01
User opened query 'Per EDC guidelines, NO must be recorded if Day 0 and Day 1 are performed on the same date, this is only entered on Day . Please verify and reconcile ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:41:12
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:07:16
User entered '02 Aug 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Aug 2020 20:32:57

US3832043

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:00:22

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User closed query 'Per CDM: If Screening visit and Dosing are done on the same day, then Pregnancy test should only be completed at the 'Screening Visit' only and marked as "No" at VID1 to avoid duplication. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:24:43
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:10:02
Query 'Per CDM: If Screening visit and Dosing are done on the same day, then Pregnancy test should only be completed at the 'Screening Visit' only and marked as "No" at VID1 to avoid duplication. Please review and update accordingly.' answered with 'Updated' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	20 Oct 2020 13:15:30
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	20 Oct 2020 13:13:53
User opened query 'Per CDM: If Screening visit and Dosing are done on the same day, then Pregnancy test should only be completed at the 'Screening Visit' only and marked as "No" at VID1 to avoid duplication. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 11:20:39
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Aug 2020 20:33:57

US3832043

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:00:22

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:10:02
User entered empty; reason for change Data Entry Error	Danyel Johnson (b) (4)	20 Oct 2020 13:13:53
User entered '02 Aug 2020'	(b) (4) Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:33:57
	(b) (4)	

US3832043

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:00:22

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:10:02
User entered empty; reason for change Data Entry Error	Danyel Johnson (b) (4)	20 Oct 2020 13:13:53
User entered 'Urine (URINE)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:33:57

US3832043

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:00:22

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:10:02
User entered empty; reason for change Data Entry Error	Danyel Johnson (b) (4)	20 Oct 2020 13:13:53
User entered 'Negative (NEGATIVE)'	(b) (4) Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:33:57

US3832043

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:00:22

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User closed query 'Per CDM: If FSH sample was not collected, Collection Date and Collection Time should be blank.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:24:45
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:10:02
Query 'Per CDM: If FSH sample was not collected, Collection Date and Collection Time should be blank.' answered with 'Updated per query' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	20 Oct 2020 13:14:33
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	20 Oct 2020 13:14:18
User entered empty; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	20 Oct 2020 13:13:53
User opened query 'Per CDM: If FSH sample was not collected, Collection Date and Collection Time should be blank.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 12:27:08
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Aug 2020 20:33:57

US3832043

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:00:22

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:10:02
User entered empty; reason for change Data Entry Error	Danyel Johnson (b) (4)	20 Oct 2020 13:13:53
User entered '02 Aug 2020'	(b) (4) Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:33:57
	(b) (4)	

US3832043

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:00:22

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:10:02
User entered empty; reason for change Data Entry Error	Danyel Johnson (b) (4)	20 Oct 2020 13:13:53
User entered '13:34'	(b) (4) Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:33:57
	(b) (4)	

US3832043

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered empty.	System	20 Oct 2020 13:13:53
User entered '02 Aug 2020 13:34'	System	02 Aug 2020 20:33:57

US3832043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:22

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:44:42
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 18:16:45

US3832043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:22

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:44:42
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Aug 2020 18:16:45

US3832043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:22

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)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:44:42
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Aug 2020 18:16:45

US3832043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:22

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'MRNA-1273 OR PLACEBO'	System	02 Aug 2020 18:16:45

US3832043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:22

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:44:42
User entered '02 Aug 2020'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 18:16:45

US3832043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:44:42
User entered '14:12'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 18:16:45

US3832043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered '02 Aug 2020 14:12'	System	02 Aug 2020 18:16:45

US3832043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:44:42
User entered 'Left Arm (LEFT ARM)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Aug 2020 18:16:45

US3832043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:44:42
User entered 'ONCE'	System	02 Aug 2020 18:16:45

US3832043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:22

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'INTRAMUSCULAR'	System	02 Aug 2020 18:16:45

US3832043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:48:04
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:34:42

US3832043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:48:04
User entered '02 Aug 2020'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:34:42

US3832043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:48:04
User entered '13:48'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:34:42

US3832043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered '02 Aug 2020 13:48'	System	02 Aug 2020 20:34:42

US3832043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:01:11
User entered '02 Aug 2020'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:35:09

US3832043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:00:22

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Aug 2020 20:35:09

US3832043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:00:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:01:11
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:35:09

US3832043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:01:11
User entered '13:47'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:35:09

US3832043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered '02 Aug 2020 13:47'	System	02 Aug 2020 20:35:09

US3832043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:00:22

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:35:09

US3832043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:00:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Un-verified.	(b) (4)	
	Alyssa-Kay Peay (b) (4)	10 Nov 2020 21:43:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Alyssa-Kay Peay (b) (4)	10 Nov 2020 21:43:22
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:01:11
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:35:09
	(b) (4)	

US3832043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:00:22

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Un-verified.	(b) (4)	
	Alyssa-Kay Peay (b) (4)	10 Nov 2020 21:43:22
User entered empty; reason for change Data Entry Error	(b) (4)	
	Alyssa-Kay Peay (b) (4)	10 Nov 2020 21:43:22
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:01:11
User entered '13:47'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:35:09
	(b) (4)	

US3832043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered empty.	System	10 Nov 2020 21:43:22
User entered '02 Aug 2020 13:47'	System	02 Aug 2020 20:35:09

US3832043

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:01:17
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	02 Aug 2020 20:35:15

US3832043

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:00:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'I'	System	02 Aug 2020 20:35:15

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	02 Aug 2020 18:16:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-02T14:47:27', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '141663bb-e875-416f-b0d9-8173c52b093e' User entered 'Yes (Y)'	System	02 Aug 2020 18:47:45
	System	02 Aug 2020 18:47:45

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-02T14:47:34', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '141663bb-e875-416f-b0d9-8173c52b093e' User entered '98.5'	System	02 Aug 2020 18:47:45
	System	02 Aug 2020 18:47:45

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-02T14:47:38', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '141663bb-e875-416f-b0d9-8173c52b093e' User entered 'No (N)'	System	02 Aug 2020 18:47:45
	System	02 Aug 2020 18:47:45

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-02T14:47:43', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '141663bb-e875-416f-b0d9-8173c52b093e' User entered '02 Aug 2020 14:47'	System	02 Aug 2020 18:47:45
	System	02 Aug 2020 18:47:45

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '02 Aug 2020 14:32'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '02 Aug 2020 17:02'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	02 Aug 2020 18:16:45
User entered 'Day 1, after vaccination (at home)'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-02T22:27:12', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '716e3017-3ab6-437f-a96d-b552a34c7f5a' User entered 'Yes (Y)'	System	03 Aug 2020 02:29:36
	System	03 Aug 2020 02:29:36

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-02T22:29:23', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '716e3017-3ab6-437f-a96d-b552a34c7f5a' User entered '97.6'	System	03 Aug 2020 02:29:36
	System	03 Aug 2020 02:29:36

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-02T22:29:29', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '716e3017-3ab6-437f-a96d-b552a34c7f5a' User entered 'No (N)'	System	03 Aug 2020 02:29:36
	System	03 Aug 2020 02:29:36

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-02T22:29:32', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '716e3017-3ab6-437f-a96d-b552a34c7f5a' User entered '02 Aug 2020 22:29'	System	03 Aug 2020 02:29:36
	System	03 Aug 2020 02:29:36

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '02 Aug 2020 17:57'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '03 Aug 2020 11:59'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	02 Aug 2020 18:16:45
User entered 'Day 2'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-03T21:38:18', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '23936065-aa36-46fb-8692-de295ba481e6' User entered 'Yes (Y)'	System	04 Aug 2020 01:38:34
	System	04 Aug 2020 01:38:34

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-03T21:38:24', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '23936065-aa36-46fb-8692-de295ba481e6' User entered '97.6'	System	04 Aug 2020 01:38:34
	System	04 Aug 2020 01:38:34

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-03T21:38:27', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '23936065-aa36-46fb-8692-de295ba481e6' User entered 'No (N)'	System	04 Aug 2020 01:38:34
	System	04 Aug 2020 01:38:34

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-03T21:38:31', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '23936065-aa36-46fb-8692-de295ba481e6' User entered '03 Aug 2020 21:38'	System	04 Aug 2020 01:38:34
	System	04 Aug 2020 01:38:34

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '03 Aug 2020 12:00'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '04 Aug 2020 11:59'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	02 Aug 2020 18:16:45
User entered 'Day 3'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:22

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '04 Aug 2020 12:00'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '05 Aug 2020 11:59'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	02 Aug 2020 18:16:45
User entered 'Day 4'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:22

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-05T14:04:50', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '5d7f9cc5-bdbb-4052-973b-7ede7d0479f0' User entered 'Yes (Y)'	System	05 Aug 2020 18:05:10
	System	05 Aug 2020 18:05:10

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-05T14:05:00', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '5d7f9cc5-bdbb-4052-973b-7ede7d0479f0' User entered '96.7'	System	05 Aug 2020 18:05:10
	System	05 Aug 2020 18:05:10

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-05T14:05:03', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '5d7f9cc5-bdbb-4052-973b-7ede7d0479f0' User entered 'No (N)'	System	05 Aug 2020 18:05:10
	System	05 Aug 2020 18:05:10

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-05T14:05:07', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '5d7f9cc5-bdbb-4052-973b-7ede7d0479f0' User entered '05 Aug 2020 14:05'	System	05 Aug 2020 18:05:10
	System	05 Aug 2020 18:05:10

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '05 Aug 2020 12:00'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '06 Aug 2020 11:59'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	02 Aug 2020 18:16:45
User entered 'Day 5'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-06T23:10:01', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'ccdb7aac-b1de-415c-8d6a-42725bdf9b3a' User entered 'Yes (Y)'	System	07 Aug 2020 03:11:31
	System	07 Aug 2020 03:11:31

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-06T23:11:17', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'ccdb7aac-b1de-415c-8d6a-42725bdf9b3a' User entered '97.8'	System	07 Aug 2020 03:11:31
	System	07 Aug 2020 03:11:31

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-06T23:11:22', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'ccdb7aac-b1de-415c-8d6a-42725bdf9b3a' User entered 'No (N)'	System	07 Aug 2020 03:11:31
	System	07 Aug 2020 03:11:31

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-06T23:11:25', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'ccdb7aac-b1de-415c-8d6a-42725bdf9b3a' User entered '06 Aug 2020 23:11'	System	07 Aug 2020 03:11:31
	System	07 Aug 2020 03:11:31

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '06 Aug 2020 12:00'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '07 Aug 2020 11:59'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	02 Aug 2020 18:16:45
User entered 'Day 6'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:22

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-07T22:04:03', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '59d03ab3-e064-4c78-a40f-212c50546149' User entered 'Yes (Y)'	System	08 Aug 2020 02:04:17
	System	08 Aug 2020 02:04:17

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-07T22:04:08', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '59d03ab3-e064-4c78-a40f-212c50546149' User entered '97.9'	System	08 Aug 2020 02:04:17
	System	08 Aug 2020 02:04:17

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-07T22:04:11', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '59d03ab3-e064-4c78-a40f-212c50546149' User entered 'No (N)'	System	08 Aug 2020 02:04:17
	System	08 Aug 2020 02:04:17

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-07T22:04:14', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '59d03ab3-e064-4c78-a40f-212c50546149' User entered '07 Aug 2020 22:04'	System	08 Aug 2020 02:04:17
	System	08 Aug 2020 02:04:17

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '07 Aug 2020 12:00'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '08 Aug 2020 11:59'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	02 Aug 2020 18:16:45
User entered 'Day 7'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-08T21:21:14', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '6646123c-2915-4490-b8c3-a6c2916c5a34' User entered 'Yes (Y)'	System	09 Aug 2020 02:21:28
	System	09 Aug 2020 02:21:28

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-08T21:21:19', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '6646123c-2915-4490-b8c3-a6c2916c5a34' User entered '98.3'	System	09 Aug 2020 02:21:28
	System	09 Aug 2020 02:21:28

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-08T21:21:21', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '6646123c-2915-4490-b8c3-a6c2916c5a34' User entered 'No (N)'	System	09 Aug 2020 02:21:28
	System	09 Aug 2020 02:21:28

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-08T21:21:24', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '6646123c-2915-4490-b8c3-a6c2916c5a34' User entered '08 Aug 2020 21:21'	System	09 Aug 2020 02:21:28
	System	09 Aug 2020 02:21:28

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '08 Aug 2020 12:00'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '09 Aug 2020 11:59'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	02 Aug 2020 18:16:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-02T14:47:55', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'd7666dcf-3564-48b3-a9fd-d9e26cbe067c' User entered 'None (1)'	System	02 Aug 2020 18:48:20
	System	02 Aug 2020 18:48:20

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-02T14:48:03', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'd7666dcf-3564-48b3-a9fd-d9e26cbe067c' User entered 'No (N)'	System	02 Aug 2020 18:48:20
	System	02 Aug 2020 18:48:20

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-02T14:48:06', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'd7666dcf-3564-48b3-a9fd-d9e26cbe067c' User entered 'No (N)'	System	02 Aug 2020 18:48:20
	System	02 Aug 2020 18:48:20

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-02T14:48:12', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'd7666dcf-3564-48b3-a9fd-d9e26cbe067c' User entered 'None (1)'	System	02 Aug 2020 18:48:20
	System	02 Aug 2020 18:48:20

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-02T14:48:19', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'd7666dcf-3564-48b3-a9fd-d9e26cbe067c' User entered '02 Aug 2020 14:48'	System	02 Aug 2020 18:48:20
	System	02 Aug 2020 18:48:20

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '02 Aug 2020 14:32'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '02 Aug 2020 17:02'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	02 Aug 2020 18:16:45
User entered 'Day 1, after vaccination (at home)'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-02T22:29:38', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'a2e056b1-19ef-431a-a27d-c9160ef04327'	System	03 Aug 2020 02:30:01
User entered 'None (1)'	System	03 Aug 2020 02:30:01

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-02T22:29:41', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'a2e056b1-19ef-431a-a27d-c9160ef04327'	System	03 Aug 2020 02:30:01
User entered 'No (N)'	System	03 Aug 2020 02:30:01

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-02T22:29:47', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'a2e056b1-19ef-431a-a27d-c9160ef04327'	System	03 Aug 2020 02:30:01
User entered 'No (N)'	System	03 Aug 2020 02:30:01

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-02T22:29:54', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'a2e056b1-19ef-431a-a27d-c9160ef04327'	System	03 Aug 2020 02:30:01
User entered 'None (1)'	System	03 Aug 2020 02:30:01

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-02T22:29:57', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'a2e056b1-19ef-431a-a27d-c9160ef04327'	System	03 Aug 2020 02:30:01
User entered '02 Aug 2020 22:29'	System	03 Aug 2020 02:30:01

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '02 Aug 2020 17:57'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '03 Aug 2020 11:59'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	02 Aug 2020 18:16:45
User entered 'Day 2'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-03T21:38:43', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'a6685fc9-9d75-4e27-bd89-14fc3e9abb59' User entered 'None (1)'	System	04 Aug 2020 01:39:16
	System	04 Aug 2020 01:39:16

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-03T21:38:57', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'a6685fc9-9d75-4e27-bd89-14fc3e9abb59' User entered 'No (N)'	System	04 Aug 2020 01:39:16
	System	04 Aug 2020 01:39:16

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-03T21:38:59', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'a6685fc9-9d75-4e27-bd89-14fc3e9abb59' User entered 'No (N)'	System	04 Aug 2020 01:39:16
	System	04 Aug 2020 01:39:16

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-03T21:39:09', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'a6685fc9-9d75-4e27-bd89-14fc3e9abb59'	System	04 Aug 2020 01:39:16
User entered 'None (1)'	System	04 Aug 2020 01:39:16

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-03T21:39:12', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'a6685fc9-9d75-4e27-bd89-14fc3e9abb59' User entered '03 Aug 2020 21:39'	System	04 Aug 2020 01:39:16
	System	04 Aug 2020 01:39:16

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '03 Aug 2020 12:00'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '04 Aug 2020 11:59'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	02 Aug 2020 18:16:45
User entered 'Day 3'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:22

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:22

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '04 Aug 2020 12:00'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '05 Aug 2020 11:59'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	02 Aug 2020 18:16:45
User entered 'Day 4'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-05T14:05:17', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '26bcf150-e479-4b06-badf-9ffd856694ff' User entered 'None (1)'	System	05 Aug 2020 18:05:33
	System	05 Aug 2020 18:05:33

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-05T14:05:22', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '26bcf150-e479-4b06-badf-9ffd856694ff' User entered 'No (N)'	System	05 Aug 2020 18:05:33
	System	05 Aug 2020 18:05:33

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-05T14:05:25', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '26bcf150-e479-4b06-badf-9ffd856694ff' User entered 'No (N)'	System	05 Aug 2020 18:05:33
	System	05 Aug 2020 18:05:33

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-05T14:05:28', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '26bcf150-e479-4b06-badf-9ffd856694ff' User entered 'None (1)'	System	05 Aug 2020 18:05:33
	System	05 Aug 2020 18:05:33

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-05T14:05:30', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '26bcf150-e479-4b06-badf-9ffd856694ff' User entered '05 Aug 2020 14:05'	System	05 Aug 2020 18:05:33
	System	05 Aug 2020 18:05:33

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '05 Aug 2020 12:00'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '06 Aug 2020 11:59'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	02 Aug 2020 18:16:45
User entered 'Day 5'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-06T23:11:31', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '793554ce-5f37-4970-bfbc-c971badbaeb5' User entered 'None (1)'	System	07 Aug 2020 03:11:47
	System	07 Aug 2020 03:11:47

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-06T23:11:33', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '793554ce-5f37-4970-bfbc-c971badbaeb5' User entered 'No (N)'	System	07 Aug 2020 03:11:47
	System	07 Aug 2020 03:11:47

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-06T23:11:36', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '793554ce-5f37-4970-bfbc-c971badbaeb5' User entered 'No (N)'	System	07 Aug 2020 03:11:47
	System	07 Aug 2020 03:11:47

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-06T23:11:39', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '793554ce-5f37-4970-bfbc-c971badbaeb5' User entered 'None (1)'	System	07 Aug 2020 03:11:47
	System	07 Aug 2020 03:11:47

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-06T23:11:42', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '793554ce-5f37-4970-bfbc-c971badbaeb5' User entered '06 Aug 2020 23:11'	System	07 Aug 2020 03:11:47
	System	07 Aug 2020 03:11:47

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '06 Aug 2020 12:00'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '07 Aug 2020 11:59'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	02 Aug 2020 18:16:45
User entered 'Day 6'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-07T22:04:18', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '237225da-b59f-481d-90bb-8087bdda474a' User entered 'None (1)'	System	08 Aug 2020 02:04:29
	System	08 Aug 2020 02:04:29

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-07T22:04:20', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '237225da-b59f-481d-90bb-8087bdda474a' User entered 'No (N)'	System	08 Aug 2020 02:04:29
	System	08 Aug 2020 02:04:29

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-07T22:04:21', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '237225da-b59f-481d-90bb-8087bdda474a' User entered 'No (N)'	System	08 Aug 2020 02:04:29
	System	08 Aug 2020 02:04:29

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-07T22:04:23', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '237225da-b59f-481d-90bb-8087bdda474a' User entered 'None (1)'	System	08 Aug 2020 02:04:29
	System	08 Aug 2020 02:04:29

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-07T22:04:26', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '237225da-b59f-481d-90bb-8087bdda474a' User entered '07 Aug 2020 22:04'	System	08 Aug 2020 02:04:29
	System	08 Aug 2020 02:04:29

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '07 Aug 2020 12:00'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '08 Aug 2020 11:59'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	02 Aug 2020 18:16:45
User entered 'Day 7'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-08T21:21:28', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'a75d9f63-1447-4d91-b0ba-d0e449b0f57f' User entered 'None (1)'	System	09 Aug 2020 02:21:46
	System	09 Aug 2020 02:21:46

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-08T21:21:32', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'a75d9f63-1447-4d91-b0ba-d0e449b0f57f' User entered 'No (N)'	System	09 Aug 2020 02:21:46
	System	09 Aug 2020 02:21:46

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-08T21:21:36', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'a75d9f63-1447-4d91-b0ba-d0e449b0f57f' User entered 'No (N)'	System	09 Aug 2020 02:21:46
	System	09 Aug 2020 02:21:46

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-08T21:21:40', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'a75d9f63-1447-4d91-b0ba-d0e449b0f57f' User entered 'None (1)'	System	09 Aug 2020 02:21:46
	System	09 Aug 2020 02:21:46

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-08T21:21:43', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'a75d9f63-1447-4d91-b0ba-d0e449b0f57f' User entered '08 Aug 2020 21:21'	System	09 Aug 2020 02:21:46
	System	09 Aug 2020 02:21:46

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '08 Aug 2020 12:00'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '09 Aug 2020 11:59'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	02 Aug 2020 18:16:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-02T14:48:29', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'd8b9fe06-d944-40ba-b61f-9a4ed3dc1a35' User entered 'None (0)'	System	02 Aug 2020 18:48:51
	System	02 Aug 2020 18:48:51

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-02T14:48:31', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'd8b9fe06-d944-40ba-b61f-9a4ed3dc1a35' User entered 'None (0)'	System	02 Aug 2020 18:48:51
	System	02 Aug 2020 18:48:51

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-02T14:48:34', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'd8b9fe06-d944-40ba-b61f-9a4ed3dc1a35'	System	02 Aug 2020 18:48:51
User entered 'None (0)'	System	02 Aug 2020 18:48:51

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-02T14:48:36', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'd8b9fe06-d944-40ba-b61f-9a4ed3dc1a35' User entered 'None (0)'	System	02 Aug 2020 18:48:51
	System	02 Aug 2020 18:48:51

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-02T14:48:38', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'd8b9fe06-d944-40ba-b61f-9a4ed3dc1a35' User entered 'None (0)'	System	02 Aug 2020 18:48:51
	System	02 Aug 2020 18:48:51

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-02T14:48:41', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'd8b9fe06-d944-40ba-b61f-9a4ed3dc1a35' User entered 'None (0)'	System	02 Aug 2020 18:48:51
	System	02 Aug 2020 18:48:51

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-02T14:48:46', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'd8b9fe06-d944-40ba-b61f-9a4ed3dc1a35'	System	02 Aug 2020 18:48:51
User entered 'No (N)'	System	02 Aug 2020 18:48:51

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-02T14:48:50', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'd8b9fe06-d944-40ba-b61f-9a4ed3dc1a35' User entered '02 Aug 2020 14:48'	System	02 Aug 2020 18:48:51
	System	02 Aug 2020 18:48:51

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '02 Aug 2020 14:32'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '02 Aug 2020 17:02'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	02 Aug 2020 18:16:45
User entered 'Day 1, after vaccination (at home)'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-02T22:30:21', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '4efc0782-fcdd-4a51-8461-99cdf940bfe'	System	03 Aug 2020 02:30:45
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	03 Aug 2020 02:30:45

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-02T22:30:25', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '4efc0782-fcdd-4a51-8461-99cdff940bfe' User entered 'None (0)'	System	03 Aug 2020 02:30:45
	System	03 Aug 2020 02:30:45

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-02T22:30:27', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '4efc0782-fcdd-4a51-8461-99cdf940bfe' User entered 'None (0)'	System	03 Aug 2020 02:30:45
	System	03 Aug 2020 02:30:45

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-02T22:30:29', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '4efc0782-fcdd-4a51-8461-99cdf940bfe' User entered 'None (0)'	System	03 Aug 2020 02:30:45
	System	03 Aug 2020 02:30:45

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-02T22:30:32', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '4efc0782-fcdd-4a51-8461-99cdf940bfe' User entered 'None (0)'	System	03 Aug 2020 02:30:45
	System	03 Aug 2020 02:30:45

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-02T22:30:34', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '4efc0782-fcdd-4a51-8461-99cdf940bfe' User entered 'None (0)'	System	03 Aug 2020 02:30:45
	System	03 Aug 2020 02:30:45

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-02T22:30:39', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '4efc0782-fcdd-4a51-8461-99cdf940bfe'	System	03 Aug 2020 02:30:45
User entered 'No (N)'	System	03 Aug 2020 02:30:45

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-02T22:30:43', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '4efc0782-fcdd-4a51-8461-99cdf940bfe'	System	03 Aug 2020 02:30:45
User entered '02 Aug 2020 22:30'	System	03 Aug 2020 02:30:45

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '02 Aug 2020 17:57'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '03 Aug 2020 11:59'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	02 Aug 2020 18:16:45
User entered 'Day 2'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-03T21:39:16', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '997caff7-07c8-4a42-a9ce-f9792321f0c1' User entered 'None (0)'	System	04 Aug 2020 01:39:39
	System	04 Aug 2020 01:39:39

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-03T21:39:18', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '997caff7-07c8-4a42-a9ce-f9792321f0c1' User entered 'None (0)'	System	04 Aug 2020 01:39:39
	System	04 Aug 2020 01:39:39

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-03T21:39:21', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '997caff7-07c8-4a42-a9ce-f9792321f0c1' User entered 'None (0)'	System	04 Aug 2020 01:39:39
	System	04 Aug 2020 01:39:39

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-03T21:39:24', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '997caff7-07c8-4a42-a9ce-f9792321f0c1' User entered 'None (0)'	System	04 Aug 2020 01:39:39
	System	04 Aug 2020 01:39:39

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-03T21:39:26', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '997caff7-07c8-4a42-a9ce-f9792321f0c1' User entered 'None (0)'	System	04 Aug 2020 01:39:39
	System	04 Aug 2020 01:39:39

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-03T21:39:28', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '997caff7-07c8-4a42-a9ce-f9792321f0c1' User entered 'None (0)'	System	04 Aug 2020 01:39:39
	System	04 Aug 2020 01:39:39

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-03T21:39:31', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '997caff7-07c8-4a42-a9ce-f9792321f0c1' User entered 'No (N)'	System	04 Aug 2020 01:39:39
	System	04 Aug 2020 01:39:39

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-03T21:39:36', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '997caff7-07c8-4a42-a9ce-f9792321f0c1' User entered '03 Aug 2020 21:39'	System	04 Aug 2020 01:39:39
	System	04 Aug 2020 01:39:39

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '03 Aug 2020 12:00'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '04 Aug 2020 11:59'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	02 Aug 2020 18:16:45
User entered 'Day 3'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '04 Aug 2020 12:00'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '05 Aug 2020 11:59'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	02 Aug 2020 18:16:45
User entered 'Day 4'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-05T14:05:34', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '77c70014-bf69-4e78-a58f-c1c07ffc3179' User entered 'None (0)'	System	05 Aug 2020 18:05:52
	System	05 Aug 2020 18:05:52

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-05T14:05:36', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '77c70014-bf69-4e78-a58f-c1c07ffc3179' User entered 'None (0)'	System	05 Aug 2020 18:05:52
	System	05 Aug 2020 18:05:52

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-05T14:05:38', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '77c70014-bf69-4e78-a58f-c1c07ffc3179' User entered 'None (0)'	System	05 Aug 2020 18:05:52
	System	05 Aug 2020 18:05:52

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-05T14:05:40', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '77c70014-bf69-4e78-a58f-c1c07ffc3179' User entered 'None (0)'	System	05 Aug 2020 18:05:52
	System	05 Aug 2020 18:05:52

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-05T14:05:42', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '77c70014-bf69-4e78-a58f-c1c07ffc3179' User entered 'None (0)'	System	05 Aug 2020 18:05:52
	System	05 Aug 2020 18:05:52

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-05T14:05:43', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '77c70014-bf69-4e78-a58f-c1c07ffc3179' User entered 'None (0)'	System	05 Aug 2020 18:05:52
	System	05 Aug 2020 18:05:52

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-05T14:05:47', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '77c70014-bf69-4e78-a58f-c1c07ffc3179' User entered 'No (N)'	System	05 Aug 2020 18:05:52
	System	05 Aug 2020 18:05:52

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-05T14:05:50', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '77c70014-bf69-4e78-a58f-c1c07ffc3179'	System	05 Aug 2020 18:05:52
User entered '05 Aug 2020 14:05'	System	05 Aug 2020 18:05:52

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '05 Aug 2020 12:00'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '06 Aug 2020 11:59'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	02 Aug 2020 18:16:45
User entered 'Day 5'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-06T23:11:46', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '2c708ebc-0a18-4d28-8186-b2c15611dfb9' User entered 'None (0)'	System	07 Aug 2020 03:12:09
	System	07 Aug 2020 03:12:09

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-06T23:11:49', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '2c708ebc-0a18-4d28-8186-b2c15611dfb9' User entered 'None (0)'	System	07 Aug 2020 03:12:09
	System	07 Aug 2020 03:12:09

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-06T23:11:51', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '2c708ebc-0a18-4d28-8186-b2c15611dfb9' User entered 'None (0)'	System	07 Aug 2020 03:12:09
	System	07 Aug 2020 03:12:09

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-06T23:11:53', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '2c708ebc-0a18-4d28-8186-b2c15611dfb9' User entered 'None (0)'	System	07 Aug 2020 03:12:09
	System	07 Aug 2020 03:12:09

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-06T23:11:55', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '2c708ebc-0a18-4d28-8186-b2c15611dfb9' User entered 'None (0)'	System	07 Aug 2020 03:12:09
	System	07 Aug 2020 03:12:09

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-06T23:11:57', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '2c708ebc-0a18-4d28-8186-b2c15611dfb9' User entered 'None (0)'	System	07 Aug 2020 03:12:09
	System	07 Aug 2020 03:12:09

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-06T23:12:02', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '2c708ebc-0a18-4d28-8186-b2c15611dfb9' User entered 'No (N)'	System	07 Aug 2020 03:12:09
	System	07 Aug 2020 03:12:09

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-06T23:12:05', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '2c708ebc-0a18-4d28-8186-b2c15611dfb9' User entered '06 Aug 2020 23:12'	System	07 Aug 2020 03:12:09
	System	07 Aug 2020 03:12:09

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '06 Aug 2020 12:00'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '07 Aug 2020 11:59'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	02 Aug 2020 18:16:45
User entered 'Day 6'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-07T22:04:31', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '4e89c0c2-51a7-48da-a623-2c7c013512db' User entered 'None (0)'	System	08 Aug 2020 02:04:51
	System	08 Aug 2020 02:04:51

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-07T22:04:33', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '4e89c0c2-51a7-48da-a623-2c7c013512db' User entered 'None (0)'	System	08 Aug 2020 02:04:51
	System	08 Aug 2020 02:04:51

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-07T22:04:35', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '4e89c0c2-51a7-48da-a623-2c7c013512db' User entered 'None (0)'	System	08 Aug 2020 02:04:51
	System	08 Aug 2020 02:04:51

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-07T22:04:36', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '4e89c0c2-51a7-48da-a623-2c7c013512db' User entered 'None (0)'	System	08 Aug 2020 02:04:51
	System	08 Aug 2020 02:04:51

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-07T22:04:38', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '4e89c0c2-51a7-48da-a623-2c7c013512db' User entered 'None (0)'	System	08 Aug 2020 02:04:51
	System	08 Aug 2020 02:04:51

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-07T22:04:39', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '4e89c0c2-51a7-48da-a623-2c7c013512db' User entered 'None (0)'	System	08 Aug 2020 02:04:51
	System	08 Aug 2020 02:04:51

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-07T22:04:41', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '4e89c0c2-51a7-48da-a623-2c7c013512db' User entered 'No (N)'	System	08 Aug 2020 02:04:51
	System	08 Aug 2020 02:04:51

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-07T22:04:47', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '4e89c0c2-51a7-48da-a623-2c7c013512db' User entered '07 Aug 2020 22:04'	System	08 Aug 2020 02:04:51
	System	08 Aug 2020 02:04:51

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '07 Aug 2020 12:00'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '08 Aug 2020 11:59'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	02 Aug 2020 18:16:45
User entered 'Day 7'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-08T21:21:47', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '7625350c-affc-4726-ab32-49826f1db0cd' User entered 'None (0)'	System	09 Aug 2020 02:22:06
	System	09 Aug 2020 02:22:06

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-08T21:21:49', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '7625350c-affc-4726-ab32-49826f1db0cd' User entered 'None (0)'	System	09 Aug 2020 02:22:06
	System	09 Aug 2020 02:22:06

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-08T21:21:51', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '7625350c-affc-4726-ab32-49826f1db0cd' User entered 'None (0)'	System	09 Aug 2020 02:22:06
	System	09 Aug 2020 02:22:06

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-08T21:21:52', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '7625350c-affc-4726-ab32-49826f1db0cd' User entered 'None (0)'	System	09 Aug 2020 02:22:06
	System	09 Aug 2020 02:22:06

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-08T21:21:55', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '7625350c-affc-4726-ab32-49826f1db0cd' User entered 'None (0)'	System	09 Aug 2020 02:22:06
	System	09 Aug 2020 02:22:06

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-08T21:21:56', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '7625350c-affc-4726-ab32-49826f1db0cd' User entered 'None (0)'	System	09 Aug 2020 02:22:06
	System	09 Aug 2020 02:22:06

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-08T21:21:59', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '7625350c-affc-4726-ab32-49826f1db0cd' User entered 'No (N)'	System	09 Aug 2020 02:22:06
	System	09 Aug 2020 02:22:06

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-08-08T21:22:02', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '7625350c-affe-4726-ab32-49826f1db0cd' User entered '08 Aug 2020 21:22'	System	09 Aug 2020 02:22:06
	System	09 Aug 2020 02:22:06

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '08 Aug 2020 12:00'	System	02 Aug 2020 18:16:45

US3832043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '09 Aug 2020 11:59'	System	02 Aug 2020 18:16:45

US3832043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:01:43
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 14:28:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Aug 2020 14:28:42
User entered 'Yes (Y)' reason for change: Per Query Resolution	Ashten Sheriff (b) (4) (b) (4)	17 Aug 2020 14:28:42
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 15:33:32
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	10 Aug 2020 15:33:32
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	10 Aug 2020 15:32:24

US3832043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:01:43
User entered '10 Aug 2020' reason for change: Per Query Resolution	Ashten Sheriff (b) (4)	17 Aug 2020 14:28:42
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered '10 Aug 2020'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 15:33:32
	(b) (4)	10 Aug 2020 15:32:24

US3832043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:01:43
User entered 'Contact Made (CONTACT MADE)' reason for change: Per Query Resolution	Ashten Sheriff (b) (4) (b) (4)	17 Aug 2020 14:28:42
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	10 Aug 2020 15:33:32
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4) (b) (4)	10 Aug 2020 15:32:24

US3832043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:01:43
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 15:32:24

US3832043

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:02:49
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 14:28:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Aug 2020 14:28:59
User entered 'Yes (Y)' reason for change: Per Query Resolution	Ashten Sheriff (b) (4) (b) (4)	17 Aug 2020 14:28:59
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 15:33:15
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	10 Aug 2020 15:33:15
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	10 Aug 2020 15:32:14

US3832043

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered '1'	System	17 Aug 2020 14:28:59
User entered empty.	System	10 Aug 2020 15:33:15
User entered '1'	System	10 Aug 2020 15:32:14

US3832043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:03:23
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 22:57:28

US3832043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:03:23
User entered '18 Aug 2020'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 22:57:28

US3832043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:03:23
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 22:57:28

US3832043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:03:23
User entered empty.	Alyssa-Kay Peay (b) (4)	18 Aug 2020 22:57:28

US3832043

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 22:57:22

US3832043

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'I'	System	18 Aug 2020 22:57:22

US3832043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered 'Yes (Y)'	(b) (4)	23 Aug 2020 21:59:16
	(b) (4), (b) (6)	

US3832043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered '23 Aug 2020'	(b) (4)	23 Aug 2020 21:59:16
	(b) (4), (b) (6)	

US3832043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Aug 2020 21:59:16

US3832043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered empty.	(b) (4)	23 Aug 2020 21:59:16
	(b) (4), (b) (6)	

US3832043

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered 'Yes (Y)'	(b) (4)	23 Aug 2020 21:59:19
	(b) (4), (b) (6)	

US3832043

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'I'	System	23 Aug 2020 21:59:19

US3832043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 17:21:04

US3832043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '4 Sep 2020'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 17:21:04

US3832043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'Clinic (Clinic)'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 17:21:04

US3832043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:22

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'VISIT2'	System	04 Sep 2020 17:21:04

US3832043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:22

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User accepted default value 'Pre-Dose (PREDOSE)'	Alyssa-Kay Peay (b) (4) (b) (4)	04 Sep 2020 18:49:58

US3832043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	04 Sep 2020 18:49:58

US3832043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '4 Sep 2020'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 18:49:58

US3832043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '13:34'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 18:49:58

US3832043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered '4 Sep 2020 13:34'	System	04 Sep 2020 18:49:58

US3832043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '98.1' F	Alyssa-Kay Peay (b) (4)	04 Sep 2020 18:49:58

US3832043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'Oral (Oral)'	(b) (4) Alyssa-Kay Peay (b) (4)	04 Sep 2020 18:49:58

US3832043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered empty.	Alyssa-Kay Peay (b) (4)	04 Sep 2020 18:49:58

US3832043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '76'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 18:49:58

US3832043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'bpm'	System	04 Sep 2020 18:49:58

US3832043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '14'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 18:49:58

US3832043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'breaths/min'	System	04 Sep 2020 18:49:58

US3832043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '116'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 18:49:58

US3832043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'mmHg'	System	04 Sep 2020 18:49:58

US3832043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '75'	(b) (4) Alyssa-Kay Peay (b) (4)	04 Sep 2020 18:49:58

US3832043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:22

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'mmHg'	System	04 Sep 2020 18:49:58

US3832043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:22

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User accepted default value 'Post-Dose (POSTDOSE)'	Alyssa-Kay Peay (b) (4) (b) (4)	04 Sep 2020 18:49:58

US3832043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	04 Sep 2020 18:49:58

US3832043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '4 Sep 2020'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 18:49:58

US3832043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '14:45'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 18:49:58

US3832043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered '4 Sep 2020 14:45'	System	04 Sep 2020 18:49:58

US3832043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '98.0' F	Alyssa-Kay Peay (b) (4)	04 Sep 2020 18:49:58

US3832043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'Oral (Oral)'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 18:49:58

US3832043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered empty.	Alyssa-Kay Peay (b) (4)	04 Sep 2020 18:49:58

US3832043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '76'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 18:49:58

US3832043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'bpm'	System	04 Sep 2020 18:49:58

US3832043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '14'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 18:49:58

US3832043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'breaths/min'	System	04 Sep 2020 18:49:58

US3832043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '115'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 18:49:58

US3832043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'mmHg'	System	04 Sep 2020 18:49:58

US3832043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '80'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 18:49:58

US3832043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:22

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'mmHg'	System	04 Sep 2020 18:49:58

US3832043

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	04 Sep 2020 17:26:35

US3832043

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:22

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '4 Sep 2020'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 17:26:35

US3832043

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:00:22

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 17:53:25

US3832043

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:00:22

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '4 Sep 2020'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 17:53:25

US3832043

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:00:22

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'Urine (URINE)'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 17:53:25

US3832043

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:00:22

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'Negative (NEGATIVE)'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 17:53:25

US3832043

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:00:22

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 17:53:25

US3832043

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:00:22

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered empty.	Alyssa-Kay Peay (b) (4)	04 Sep 2020 17:53:25

US3832043

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:00:22

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered empty.	Alyssa-Kay Peay (b) (4)	04 Sep 2020 17:53:25

US3832043

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered empty.	System	04 Sep 2020 17:53:25

US3832043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:22

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	04 Sep 2020 18:15:18

US3832043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:22

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered empty.	Alyssa-Kay Peay (b) (4)	04 Sep 2020 18:15:18

US3832043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:22

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)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered empty.	Alyssa-Kay Peay (b) (4)	04 Sep 2020 18:15:18

US3832043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:22

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 18:15:18

US3832043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:22

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '4 Sep 2020'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 18:15:18

US3832043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '14:13'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 18:15:18

US3832043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered '4 Sep 2020 14:13'	System	04 Sep 2020 18:15:18

US3832043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:22

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'Left Arm (LEFT ARM)'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 18:15:18

US3832043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'ONCE'	System	04 Sep 2020 18:15:18

US3832043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:22

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 18:15:18

US3832043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	04 Sep 2020 18:12:06

US3832043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '4 Sep 2020'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 18:12:06

US3832043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '14:11'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 18:12:06

US3832043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered '4 Sep 2020 14:11'	System	04 Sep 2020 18:12:06

US3832043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:00:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '4 Sep 2020'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 18:10:31

US3832043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:00:22

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alyssa-Kay Peay (b) (4) (b) (4)	04 Sep 2020 18:10:31

US3832043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:00:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 18:10:31

US3832043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '14:10'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 18:10:31

US3832043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered '4 Sep 2020 14:10'	System	04 Sep 2020 18:10:31

US3832043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:00:22

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 18:10:31

US3832043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:00:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Alyssa-Kay Peay (b) (4)	10 Nov 2020 21:43:36
User entered 'Yes (Y)'	(b) (4)	
	Alyssa-Kay Peay (b) (4)	04 Sep 2020 18:10:31
	(b) (4)	

US3832043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4)	10 Nov 2020 21:43:36
User entered '14:10'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 18:10:31

US3832043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered empty.	System	10 Nov 2020 21:43:36
User entered '4 Sep 2020 14:10'	System	04 Sep 2020 18:10:31

US3832043

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 17:26:46

US3832043

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'I'	System	04 Sep 2020 17:26:46

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	04 Sep 2020 18:15:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-04T14:48:04', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '031df36d-74a3-4404-bab5-20322eccf14b' User entered 'Yes (Y)'	System	04 Sep 2020 18:48:17
	System	04 Sep 2020 18:48:17

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-04T14:48:09', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '031df36d-74a3-4404-bab5-20322eccf14b' User entered '98.0'	System	04 Sep 2020 18:48:17
	System	04 Sep 2020 18:48:17

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-04T14:48:12', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '031df36d-74a3-4404-bab5-20322eccf14b' User entered 'No (N)'	System	04 Sep 2020 18:48:17
	System	04 Sep 2020 18:48:17

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-04T14:48:16', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '031df36d-74a3-4404-bab5-20322eccf14b' User entered '04 Sep 2020 14:48'	System	04 Sep 2020 18:48:17
	System	04 Sep 2020 18:48:17

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '04 Sep 2020 14:33'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '04 Sep 2020 17:03'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	04 Sep 2020 18:15:18
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-04T22:01:27', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'cd74762d-94f3-49d9-8181-97b4e3af3f2c' User entered 'Yes (Y)'	System	05 Sep 2020 02:01:46
	System	05 Sep 2020 02:01:46

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-04T22:01:31', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'cd74762d-94f3-49d9-8181-97b4e3af3f2c' User entered '97.5'	System	05 Sep 2020 02:01:46
	System	05 Sep 2020 02:01:46

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-04T22:01:34', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'cd74762d-94f3-49d9-8181-97b4e3af3f2c' User entered 'No (N)'	System	05 Sep 2020 02:01:46
	System	05 Sep 2020 02:01:46

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-04T22:01:36', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'cd74762d-94f3-49d9-8181-97b4e3af3f2c' User entered '04 Sep 2020 22:01'	System	05 Sep 2020 02:01:46
	System	05 Sep 2020 02:01:46

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '04 Sep 2020 17:58'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	04 Sep 2020 18:15:18
User entered 'Day 2'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-05T21:34:46', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '93377e10-17ad-41c7-98cd-3601f97273f6' User entered 'Yes (Y)'	System	06 Sep 2020 01:35:06
	System	06 Sep 2020 01:35:06

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-05T21:34:50', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '93377e10-17ad-41c7-98cd-3601f97273f6' User entered '101.2'	System	06 Sep 2020 01:35:06
	System	06 Sep 2020 01:35:06

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-05T21:34:55', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '93377e10-17ad-41c7-98cd-3601f97273f6' User entered 'Yes (Y)'	System	06 Sep 2020 01:35:06
	System	06 Sep 2020 01:35:06

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'subject reported taking Advil. Con meds updated accordingly. ' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 11:05:46
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-05T21:35:00', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '93377e10-17ad-41c7-98cd-3601f97273f6' User entered '1'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Oct 2020 11:49:22
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	06 Sep 2020 01:35:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-05T21:35:00', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '93377e10-17ad-41c7-98cd-3601f97273f6' User entered '1'	System	06 Sep 2020 01:35:06
User entered '1'	System	06 Sep 2020 01:35:06

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:22

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-05T21:35:00', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '93377e10-17ad-41c7-98cd-3601f97273f6' User entered '0'	System	06 Sep 2020 01:35:06
	System	06 Sep 2020 01:35:06

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-05T21:35:03', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '93377e10-17ad-41c7-98cd-3601f97273f6' User entered '05 Sep 2020 21:35'	System	06 Sep 2020 01:35:06
	System	06 Sep 2020 01:35:06

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	04 Sep 2020 18:15:18
User entered 'Day 3'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-06T22:30:48', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'b2b675fd-7c45-4f20-bc55-a697826b2ebf' User entered 'Yes (Y)'	System	07 Sep 2020 02:31:00
	System	07 Sep 2020 02:31:00

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-06T22:30:52', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'b2b675fd-7c45-4f20-bc55-a697826b2ebf' User entered '99.0'	System	07 Sep 2020 02:31:00
	System	07 Sep 2020 02:31:00

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-06T22:30:55', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'b2b675fd-7c45-4f20-bc55-a697826b2ebf' User entered 'No (N)'	System	07 Sep 2020 02:31:00
	System	07 Sep 2020 02:31:00

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-06T22:30:57', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'b2b675fd-7c45-4f20-bc55-a697826b2ebf' User entered '06 Sep 2020 22:30'	System	07 Sep 2020 02:31:00
	System	07 Sep 2020 02:31:00

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	04 Sep 2020 18:15:18
User entered 'Day 4'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-08T00:01:16', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '9f1a05c0-c219-4f01-b083-ea5edb3aa2b0' User entered 'Yes (Y)'	System	08 Sep 2020 04:01:29
	System	08 Sep 2020 04:01:29

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-08T00:01:20', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '9f1a05c0-c219-4f01-b083-ea5edb3aa2b0' User entered '96.9'	System	08 Sep 2020 04:01:29
	System	08 Sep 2020 04:01:29

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-08T00:01:22', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '9f1a05c0-c219-4f01-b083-ea5edb3aa2b0'	System	08 Sep 2020 04:01:29
User entered 'No (N)'	System	08 Sep 2020 04:01:29

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-08T00:01:25', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '9f1a05c0-c219-4f01-b083-ea5edb3aa2b0' User entered '08 Sep 2020 00:01'	System	08 Sep 2020 04:01:29
	System	08 Sep 2020 04:01:29

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	04 Sep 2020 18:15:18
User entered 'Day 5'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-08T23:59:28', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '0606a1d8-c538-4825-8d56-3705b9833c93' User entered 'Yes (Y)'	System	09 Sep 2020 03:59:41
	System	09 Sep 2020 03:59:41

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-08T23:59:33', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '0606a1d8-c538-4825-8d56-3705b9833c93' User entered '97.2'	System	09 Sep 2020 03:59:41
	System	09 Sep 2020 03:59:41

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-08T23:59:36', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '0606a1d8-c538-4825-8d56-3705b9833c93'	System	09 Sep 2020 03:59:41
User entered 'No (N)'	System	09 Sep 2020 03:59:41

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-08T23:59:39', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '0606a1d8-c538-4825-8d56-3705b9833c93' User entered '08 Sep 2020 23:59'	System	09 Sep 2020 03:59:41
	System	09 Sep 2020 03:59:41

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	04 Sep 2020 18:15:18
User entered 'Day 6'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-10T00:58:49', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '90884c5e-41bc-41b1-91c3-ed3575d462a4' User entered 'Yes (Y)'	System	10 Sep 2020 04:59:04
	System	10 Sep 2020 04:59:04

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-10T00:58:55', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '90884c5e-41bc-41b1-91c3-ed3575d462a4' User entered '97.2'	System	10 Sep 2020 04:59:04
	System	10 Sep 2020 04:59:04

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-10T00:58:58', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '90884c5e-41bc-41b1-91c3-ed3575d462a4' User entered 'No (N)'	System	10 Sep 2020 04:59:04
	System	10 Sep 2020 04:59:04

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-10T00:59:00', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '90884c5e-41bc-41b1-91c3-ed3575d462a4' User entered '10 Sep 2020 00:59'	System	10 Sep 2020 04:59:04
	System	10 Sep 2020 04:59:04

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	04 Sep 2020 18:15:18
User entered 'Day 7'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-10T23:07:25', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'bfb43328-02c5-4392-8b43-c2dac40167af' User entered 'Yes (Y)'	System	11 Sep 2020 03:07:39
	System	11 Sep 2020 03:07:39

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-10T23:07:30', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'bfb43328-02c5-4392-8b43-c2dac40167af' User entered '96.3'	System	11 Sep 2020 03:07:39
	System	11 Sep 2020 03:07:39

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-10T23:07:34', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'bfb43328-02c5-4392-8b43-c2dac40167af' User entered 'No (N)'	System	11 Sep 2020 03:07:39
	System	11 Sep 2020 03:07:39

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-10T23:07:36', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'bfb43328-02c5-4392-8b43-c2dac40167af' User entered '10 Sep 2020 23:07'	System	11 Sep 2020 03:07:39
	System	11 Sep 2020 03:07:39

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	04 Sep 2020 18:15:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-04T14:48:22', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '94bcf87b-45e5-4fb9-b75a-a8fe24a3cb56' User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 18:48:40
	System	04 Sep 2020 18:48:40

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-04T14:48:28', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '94bcf87b-45e5-4fb9-b75a-a8fe24a3cb56' User entered 'No (N)'	System	04 Sep 2020 18:48:40
	System	04 Sep 2020 18:48:40

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-04T14:48:30', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '94bcf87b-45e5-4fb9-b75a-a8fe24a3cb56' User entered 'No (N)'	System	04 Sep 2020 18:48:40
	System	04 Sep 2020 18:48:40

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-04T14:48:34', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '94bcf87b-45e5-4fb9-b75a-a8fe24a3cb56' User entered 'None (1)'	System	04 Sep 2020 18:48:40
	System	04 Sep 2020 18:48:40

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-04T14:48:36', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '94bcf87b-45e5-4fb9-b75a-a8fe24a3cb56' User entered '04 Sep 2020 14:48'	System	04 Sep 2020 18:48:40
	System	04 Sep 2020 18:48:40

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '04 Sep 2020 14:33'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '04 Sep 2020 17:03'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	04 Sep 2020 18:15:18
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-04T21:59:57', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '3b1f7d2e-f74d-4670-b379-9b3afa36d224' User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 02:00:20
	System	05 Sep 2020 02:00:20

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-04T22:00:00', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '3b1f7d2e-f74d-4670-b379-9b3afa36d224' User entered 'No (N)'	System	05 Sep 2020 02:00:20
	System	05 Sep 2020 02:00:20

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-04T22:00:08', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '3b1f7d2e-f74d-4670-b379-9b3afa36d224' User entered 'No (N)'	System	05 Sep 2020 02:00:20
	System	05 Sep 2020 02:00:20

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-04T22:00:13', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '3b1f7d2e-f74d-4670-b379-9b3afa36d224' User entered 'None (1)'	System	05 Sep 2020 02:00:20
	System	05 Sep 2020 02:00:20

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-04T22:00:18', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '3b1f7d2e-f74d-4670-b379-9b3afa36d224' User entered '04 Sep 2020 22:00'	System	05 Sep 2020 02:00:20
	System	05 Sep 2020 02:00:20

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '04 Sep 2020 17:58'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	04 Sep 2020 18:15:18
User entered 'Day 2'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-05T21:35:15', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '6d9773be-a48a-45b2-8042-bf2b4c7ac877'	System	06 Sep 2020 01:38:41
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	06 Sep 2020 01:38:41

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-05T21:35:18', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '6d9773be-a48a-45b2-8042-bf2b4c7ac877' User entered 'Yes (Y)'	System	06 Sep 2020 01:38:41
	System	06 Sep 2020 01:38:41

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:22

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-05T21:38:14', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '6d9773be-a48a-45b2-8042-bf2b4c7ac877' User entered '105'	System	06 Sep 2020 01:38:41
	System	06 Sep 2020 01:38:41

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-05T21:38:17', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '6d9773be-a48a-45b2-8042-bf2b4c7ac877' User entered 'Yes (Y)'	System	06 Sep 2020 01:38:41
	System	06 Sep 2020 01:38:41

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:22

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-05T21:38:24', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '6d9773be-a48a-45b2-8042-bf2b4c7ac877' User entered '105'	System	06 Sep 2020 01:38:41
	System	06 Sep 2020 01:38:41

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-05T21:38:32', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '6d9773be-a48a-45b2-8042-bf2b4c7ac877'	System	06 Sep 2020 01:38:41
User entered 'None (1)'	System	06 Sep 2020 01:38:41

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-05T21:38:37', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '6d9773be-a48a-45b2-8042-bf2b4c7ac877' User entered '05 Sep 2020 21:38'	System	06 Sep 2020 01:38:41
	System	06 Sep 2020 01:38:41

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	04 Sep 2020 18:15:18
User entered 'Day 3'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-06T22:29:35', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '8f58170a-a433-420f-9684-028023df16c5' User entered 'Does not interfere with activity (2)'	System	07 Sep 2020 02:30:38
	System	07 Sep 2020 02:30:38

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-06T22:29:38', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '8f58170a-a433-420f-9684-028023df16c5' User entered 'Yes (Y)'	System	07 Sep 2020 02:30:38
	System	07 Sep 2020 02:30:38

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:22

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-06T22:29:44', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '8f58170a-a433-420f-9684-028023df16c5' User entered '72'	System	07 Sep 2020 02:30:38
	System	07 Sep 2020 02:30:38

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-06T22:29:48', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '8f58170a-a433-420f-9684-028023df16c5' User entered 'Yes (Y)'	System	07 Sep 2020 02:30:38
	System	07 Sep 2020 02:30:38

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:22

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-06T22:30:27', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '8f58170a-a433-420f-9684-028023df16c5' User entered '72'	System	07 Sep 2020 02:30:38
	System	07 Sep 2020 02:30:38

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-06T22:30:30', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '8f58170a-a433-420f-9684-028023df16c5' User entered 'None (1)'	System	07 Sep 2020 02:30:38
	System	07 Sep 2020 02:30:38

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-06T22:30:33', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '8f58170a-a433-420f-9684-028023df16c5' User entered '06 Sep 2020 22:30'	System	07 Sep 2020 02:30:38
	System	07 Sep 2020 02:30:38

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	04 Sep 2020 18:15:18
User entered 'Day 4'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-08T00:01:30', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'd8de42b1-691d-4de6-8589-e853233cf560'	System	08 Sep 2020 04:01:42
User entered 'None (1)'	System	08 Sep 2020 04:01:42

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-08T00:01:32', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'd8de42b1-691d-4de6-8589-e853233cf560' User entered 'No (N)'	System	08 Sep 2020 04:01:42
	System	08 Sep 2020 04:01:42

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-08T00:01:35', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'd8de42b1-691d-4de6-8589-e853233cf560' User entered 'No (N)'	System	08 Sep 2020 04:01:42
	System	08 Sep 2020 04:01:42

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-08T00:01:37', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'd8de42b1-691d-4de6-8589-e853233cf560'	System	08 Sep 2020 04:01:42
User entered 'None (1)'	System	08 Sep 2020 04:01:42

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-08T00:01:40', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'd8de42b1-691d-4de6-8589-e853233cf560' User entered '08 Sep 2020 00:01'	System	08 Sep 2020 04:01:42
	System	08 Sep 2020 04:01:42

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	04 Sep 2020 18:15:18
User entered 'Day 5'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-08T23:59:42', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '6e37a3d8-af2c-4aa5-bc40-0340fbc74162'	System	09 Sep 2020 03:59:59
User entered 'None (1)'	System	09 Sep 2020 03:59:59

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-08T23:59:45', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '6e37a3d8-af2c-4aa5-bc40-0340fbc74162'	System	09 Sep 2020 03:59:59
User entered 'No (N)'	System	09 Sep 2020 03:59:59

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-08T23:59:49', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '6e37a3d8-af2c-4aa5-bc40-0340fbc74162' User entered 'No (N)'	System	09 Sep 2020 03:59:59
	System	09 Sep 2020 03:59:59

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-08T23:59:53', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '6e37a3d8-af2c-4aa5-bc40-0340fbc74162' User entered 'None (1)'	System	09 Sep 2020 03:59:59
	System	09 Sep 2020 03:59:59

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-08T23:59:56', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '6e37a3d8-af2c-4aa5-bc40-0340fbc74162'	System	09 Sep 2020 03:59:59
User entered '08 Sep 2020 23:59'	System	09 Sep 2020 03:59:59

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	04 Sep 2020 18:15:18
User entered 'Day 6'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-10T00:58:33', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'eab6813f-888a-468f-ac3e-50c3013fb5cd' User entered 'None (1)'	System	10 Sep 2020 04:58:48
	System	10 Sep 2020 04:58:48

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-10T00:58:35', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'eab6813f-888a-468f-ac3e-50c3013fb5cd' User entered 'No (N)'	System	10 Sep 2020 04:58:48
	System	10 Sep 2020 04:58:48

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-10T00:58:38', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'eab6813f-888a-468f-ac3e-50c3013fb5cd' User entered 'No (N)'	System	10 Sep 2020 04:58:48
	System	10 Sep 2020 04:58:48

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-10T00:58:40', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'eab6813f-888a-468f-ac3e-50c3013fb5cd' User entered 'None (1)'	System	10 Sep 2020 04:58:48
	System	10 Sep 2020 04:58:48

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-10T00:58:43', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'eab6813f-888a-468f-ac3e-50c3013fb5cd' User entered '10 Sep 2020 00:58'	System	10 Sep 2020 04:58:48
	System	10 Sep 2020 04:58:48

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	04 Sep 2020 18:15:18
User entered 'Day 7'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-10T23:07:05', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'da2f5bb9-3266-4bda-8c16-69e648621987' User entered 'None (1)'	System	11 Sep 2020 03:07:18
	System	11 Sep 2020 03:07:18

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-10T23:07:08', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'da2f5bb9-3266-4bda-8c16-69e648621987' User entered 'No (N)'	System	11 Sep 2020 03:07:18
	System	11 Sep 2020 03:07:18

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-10T23:07:10', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'da2f5bb9-3266-4bda-8c16-69e648621987' User entered 'No (N)'	System	11 Sep 2020 03:07:18
	System	11 Sep 2020 03:07:18

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-10T23:07:12', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'da2f5bb9-3266-4bda-8c16-69e648621987' User entered 'None (1)'	System	11 Sep 2020 03:07:18
	System	11 Sep 2020 03:07:18

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-10T23:07:15', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'da2f5bb9-3266-4bda-8c16-69e648621987' User entered '10 Sep 2020 23:07'	System	11 Sep 2020 03:07:18
	System	11 Sep 2020 03:07:18

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	04 Sep 2020 18:15:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-04T14:48:41', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '3dc828b8-901c-4f94-a6f5-9ed3e0b68c12' User entered 'None (0)'	System	04 Sep 2020 18:49:08
	System	04 Sep 2020 18:49:08

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-04T14:48:43', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '3dc828b8-901c-4f94-a6f5-9ed3e0b68c12' User entered 'None (0)'	System	04 Sep 2020 18:49:08
	System	04 Sep 2020 18:49:08

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-04T14:48:46', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '3dc828b8-901c-4f94-a6f5-9ed3e0b68c12' User entered 'None (0)'	System	04 Sep 2020 18:49:08
	System	04 Sep 2020 18:49:08

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-04T14:48:48', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '3dc828b8-901c-4f94-a6f5-9ed3e0b68c12' User entered 'None (0)'	System	04 Sep 2020 18:49:08
	System	04 Sep 2020 18:49:08

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-04T14:48:50', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '3dc828b8-901c-4f94-a6f5-9ed3e0b68c12' User entered 'None (0)'	System	04 Sep 2020 18:49:08
	System	04 Sep 2020 18:49:08

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-04T14:48:55', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '3dc828b8-901c-4f94-a6f5-9ed3e0b68c12' User entered 'None (0)'	System	04 Sep 2020 18:49:08
	System	04 Sep 2020 18:49:08

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-04T14:49:00', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '3dc828b8-901c-4f94-a6f5-9ed3e0b68c12' User entered 'No (N)'	System	04 Sep 2020 18:49:08
	System	04 Sep 2020 18:49:08

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-04T14:49:03', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '3dc828b8-901c-4f94-a6f5-9ed3e0b68c12' User entered '04 Sep 2020 14:49'	System	04 Sep 2020 18:49:08
	System	04 Sep 2020 18:49:08

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '04 Sep 2020 14:33'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '04 Sep 2020 17:03'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	04 Sep 2020 18:15:18
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-04T21:59:31', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '0648d32e-d950-4855-a902-f239fc559d1a' User entered 'None (0)'	System	05 Sep 2020 01:59:52
	System	05 Sep 2020 01:59:52

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-04T21:59:33', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '0648d32e-d950-4855-a902-f239fc559d1a' User entered 'None (0)'	System	05 Sep 2020 01:59:52
	System	05 Sep 2020 01:59:52

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-04T21:59:36', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '0648d32e-d950-4855-a902-f239fc559d1a' User entered 'None (0)'	System	05 Sep 2020 01:59:52
	System	05 Sep 2020 01:59:52

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-04T21:59:38', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '0648d32e-d950-4855-a902-f239fc559d1a' User entered 'None (0)'	System	05 Sep 2020 01:59:52
	System	05 Sep 2020 01:59:52

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-04T21:59:41', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '0648d32e-d950-4855-a902-f239fc559d1a' User entered 'None (0)'	System	05 Sep 2020 01:59:52
	System	05 Sep 2020 01:59:52

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-04T21:59:43', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '0648d32e-d950-4855-a902-f239fc559d1a' User entered 'None (0)'	System	05 Sep 2020 01:59:52
	System	05 Sep 2020 01:59:52

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-04T21:59:46', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '0648d32e-d950-4855-a902-f239fc559d1a' User entered 'No (N)'	System	05 Sep 2020 01:59:52
	System	05 Sep 2020 01:59:52

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-04T21:59:48', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '0648d32e-d950-4855-a902-f239fc559d1a' User entered '04 Sep 2020 21:59'	System	05 Sep 2020 01:59:52
	System	05 Sep 2020 01:59:52

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '04 Sep 2020 17:58'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	04 Sep 2020 18:15:18
User entered 'Day 2'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-05T21:38:44', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '9743cc30-f891-46ad-90c7-4af1c2ff756a'	System	06 Sep 2020 01:39:17
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	06 Sep 2020 01:39:17

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-05T21:38:49', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '9743cc30-f891-46ad-90c7-4af1c2ff756a' User entered 'No interference with activity (1)'	System	06 Sep 2020 01:39:17
	System	06 Sep 2020 01:39:17

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-05T21:38:52', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '9743cc30-f891-46ad-90c7-4af1c2ff756a' User entered 'No interference with activity (1)'	System	06 Sep 2020 01:39:17
	System	06 Sep 2020 01:39:17

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-05T21:38:54', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '9743cc30-f891-46ad-90c7-4af1c2ff756a' User entered 'No interference with activity (1)'	System	06 Sep 2020 01:39:17
	System	06 Sep 2020 01:39:17

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-05T21:39:01', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '9743cc30-f891-46ad-90c7-4af1c2ff756a'	System	06 Sep 2020 01:39:17
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	06 Sep 2020 01:39:17

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-05T21:39:06', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '9743cc30-f891-46ad-90c7-4af1c2ff756a'	System	06 Sep 2020 01:39:17
User entered 'Some interference with activity not requiring medical attention (2)'	System	06 Sep 2020 01:39:17

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-05T21:39:09', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '9743cc30-f891-46ad-90c7-4af1c2ff756a' User entered 'No (N)'	System	06 Sep 2020 01:39:17
	System	06 Sep 2020 01:39:17

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-05T21:39:12', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '9743cc30-f891-46ad-90c7-4af1c2ff756a' User entered '05 Sep 2020 21:39'	System	06 Sep 2020 01:39:17
	System	06 Sep 2020 01:39:17

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	04 Sep 2020 18:15:18
User entered 'Day 3'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-06T22:28:59', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'a1c13c4e-6c22-44dd-b0ad-5f791f33d45a' User entered 'None (0)'	System	07 Sep 2020 02:29:30
	System	07 Sep 2020 02:29:30

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-06T22:29:04', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'a1c13c4e-6c22-44dd-b0ad-5f791f33d45a'	System	07 Sep 2020 02:29:30
User entered 'No interference with activity (1)'	System	07 Sep 2020 02:29:30

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-06T22:29:07', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'a1c13c4e-6c22-44dd-b0ad-5f791f33d45a' User entered 'None (0)'	System	07 Sep 2020 02:29:30
	System	07 Sep 2020 02:29:30

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-06T22:29:09', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'a1c13c4e-6c22-44dd-b0ad-5f791f33d45a' User entered 'None (0)'	System	07 Sep 2020 02:29:30
	System	07 Sep 2020 02:29:30

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-06T22:29:18', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'a1c13c4e-6c22-44dd-b0ad-5f791f33d45a'	System	07 Sep 2020 02:29:30
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	07 Sep 2020 02:29:30

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-06T22:29:21', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'a1c13c4e-6c22-44dd-b0ad-5f791f33d45a' User entered 'None (0)'	System	07 Sep 2020 02:29:30
	System	07 Sep 2020 02:29:30

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-06T22:29:24', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'a1c13c4e-6c22-44dd-b0ad-5f791f33d45a' User entered 'No (N)'	System	07 Sep 2020 02:29:30
	System	07 Sep 2020 02:29:30

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-06T22:29:28', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'a1c13c4e-6c22-44dd-b0ad-5f791f33d45a' User entered '06 Sep 2020 22:29'	System	07 Sep 2020 02:29:30
	System	07 Sep 2020 02:29:30

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	04 Sep 2020 18:15:18
User entered 'Day 4'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-08T00:01:43', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '40e16a61-ccb4-4718-ac93-826f2922cb49' User entered 'None (0)'	System	08 Sep 2020 04:02:04
	System	08 Sep 2020 04:02:04

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-08T00:01:45', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '40e16a61-ccbf-4718-ac93-826f2922cb49' User entered 'None (0)'	System	08 Sep 2020 04:02:04
	System	08 Sep 2020 04:02:04

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-08T00:01:48', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '40e16a61-ccb4-4718-ac93-826f2922cb49' User entered 'None (0)'	System	08 Sep 2020 04:02:04
	System	08 Sep 2020 04:02:04

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-08T00:01:50', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '40e16a61-ccb4-4718-ac93-826f2922cb49' User entered 'None (0)'	System	08 Sep 2020 04:02:04
	System	08 Sep 2020 04:02:04

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-08T00:01:52', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '40e16a61-ccb4-4718-ac93-826f2922cb49' User entered 'None (0)'	System	08 Sep 2020 04:02:04
	System	08 Sep 2020 04:02:04

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-08T00:01:54', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '40e16a61-ccb4-4718-ac93-826f2922cb49' User entered 'None (0)'	System	08 Sep 2020 04:02:04
	System	08 Sep 2020 04:02:04

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-08T00:01:57', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '40e16a61-ccb4-4718-ac93-826f2922cb49' User entered 'No (N)'	System	08 Sep 2020 04:02:04
	System	08 Sep 2020 04:02:04

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-08T00:02:01', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '40e16a61-ccb4-4718-ac93-826f2922cb49' User entered '08 Sep 2020 00:02'	System	08 Sep 2020 04:02:04
	System	08 Sep 2020 04:02:04

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	04 Sep 2020 18:15:18
User entered 'Day 5'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-09T00:00:02', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '1b142af7-b011-4451-9af7-f0f1437720bf' User entered 'None (0)'	System	09 Sep 2020 04:00:23
	System	09 Sep 2020 04:00:23

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-09T00:00:03', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '1b142af7-b011-4451-9af7-f0f1437720bf' User entered 'None (0)'	System	09 Sep 2020 04:00:23
	System	09 Sep 2020 04:00:23

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-09T00:00:06', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '1b142af7-b011-4451-9af7-f0f1437720bf' User entered 'None (0)'	System	09 Sep 2020 04:00:23
	System	09 Sep 2020 04:00:23

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-09T00:00:08', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '1b142af7-b011-4451-9af7-f0f1437720bf' User entered 'None (0)'	System	09 Sep 2020 04:00:23
	System	09 Sep 2020 04:00:23

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-09T00:00:09', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '1b142af7-b011-4451-9af7-f0f1437720bf' User entered 'None (0)'	System	09 Sep 2020 04:00:23
	System	09 Sep 2020 04:00:23

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-09T00:00:11', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '1b142af7-b011-4451-9af7-f0f1437720bf' User entered 'None (0)'	System	09 Sep 2020 04:00:23
	System	09 Sep 2020 04:00:23

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-09T00:00:13', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '1b142af7-b011-4451-9af7-f0f1437720bf' User entered 'No (N)'	System	09 Sep 2020 04:00:23
	System	09 Sep 2020 04:00:23

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-09T00:00:15', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '1b142af7-b011-4451-9af7-f0f1437720bf' User entered '09 Sep 2020 00:00'	System	09 Sep 2020 04:00:23
	System	09 Sep 2020 04:00:23

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	04 Sep 2020 18:15:18
User entered 'Day 6'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-10T00:58:15', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '33063e17-1add-4823-b61d-face5f97ac3d' User entered 'None (0)'	System	10 Sep 2020 04:58:31
	System	10 Sep 2020 04:58:31

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-10T00:58:17', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '33063e17-1add-4823-b61d-face5f97ac3d' User entered 'None (0)'	System	10 Sep 2020 04:58:31
	System	10 Sep 2020 04:58:31

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-10T00:58:19', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '33063e17-1add-4823-b61d-face5f97ac3d' User entered 'None (0)'	System	10 Sep 2020 04:58:31
	System	10 Sep 2020 04:58:31

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-10T00:58:20', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '33063e17-1add-4823-b61d-face5f97ac3d' User entered 'None (0)'	System	10 Sep 2020 04:58:31
	System	10 Sep 2020 04:58:31

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-10T00:58:22', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '33063e17-1add-4823-b61d-face5f97ac3d' User entered 'None (0)'	System	10 Sep 2020 04:58:31
	System	10 Sep 2020 04:58:31

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-10T00:58:24', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '33063e17-1add-4823-b61d-face5f97ac3d' User entered 'None (0)'	System	10 Sep 2020 04:58:31
	System	10 Sep 2020 04:58:31

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-10T00:58:26', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '33063e17-1add-4823-b61d-face5f97ac3d' User entered 'No (N)'	System	10 Sep 2020 04:58:31
	System	10 Sep 2020 04:58:31

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-10T00:58:29', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '33063e17-1add-4823-b61d-face5f97ac3d' User entered '10 Sep 2020 00:58'	System	10 Sep 2020 04:58:31
	System	10 Sep 2020 04:58:31

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	04 Sep 2020 18:15:18
User entered 'Day 7'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-10T23:06:45', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '09daee5e-d108-4b90-9d6c-be92ff058260' User entered 'None (0)'	System	11 Sep 2020 03:07:05
	System	11 Sep 2020 03:07:05

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-10T23:06:47', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '09daee5e-d108-4b90-9d6c-be92ff058260' User entered 'None (0)'	System	11 Sep 2020 03:07:05
	System	11 Sep 2020 03:07:05

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-10T23:06:49', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '09daee5e-d108-4b90-9d6c-be92ff058260' User entered 'None (0)'	System	11 Sep 2020 03:07:05
	System	11 Sep 2020 03:07:05

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-10T23:06:51', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '09daee5e-d108-4b90-9d6c-be92ff058260' User entered 'None (0)'	System	11 Sep 2020 03:07:05
	System	11 Sep 2020 03:07:05

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-10T23:06:55', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '09daee5e-d108-4b90-9d6c-be92ff058260' User entered 'None (0)'	System	11 Sep 2020 03:07:05
	System	11 Sep 2020 03:07:05

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-10T23:06:57', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '09daee5e-d108-4b90-9d6c-be92ff058260' User entered 'None (0)'	System	11 Sep 2020 03:07:05
	System	11 Sep 2020 03:07:05

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:22

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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-10T23:06:59', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '09daee5e-d108-4b90-9d6c-be92ff058260' User entered 'No (N)'	System	11 Sep 2020 03:07:05
	System	11 Sep 2020 03:07:05

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-09-10T23:07:02', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '09daee5e-d108-4b90-9d6c-be92ff058260' User entered '10 Sep 2020 23:07'	System	11 Sep 2020 03:07:05
	System	11 Sep 2020 03:07:05

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 18:15:18

US3832043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 18:15:18

US3832043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:28:45

US3832043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	19 Oct 2020 20:54:13
User entered '11 Sep 2020' reason for change: Data Entry Error	System	19 Oct 2020 20:54:13
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	Danyel Johnson (b) (4)	19 Oct 2020 20:54:13
User entered '8 Sep 2020'	(b) (4)	
	System	15 Sep 2020 15:28:45
	Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:28:45
	(b) (4)	

US3832043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:28:45

US3832043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered empty.	Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:28:45

US3832043

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:28:16

US3832043

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'I'	System	15 Sep 2020 15:28:16

US3832043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:29:01

US3832043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	System	20 Sep 2020 18:40:14
answered by data change (Site from System).		
User entered '18 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Sep 2020 18:40:14
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	15 Sep 2020 15:29:01
User entered '15 Sep 2020'	Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:29:01
	(b) (4)	

US3832043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:29:01

US3832043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered empty.	Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:29:01

US3832043

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:29:07

US3832043

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'I'	System	15 Sep 2020 15:29:07

US3832043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	25 Sep 2020 14:22:26

US3832043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '25 Sep 2020'	Alyssa-Kay Peay (b) (4)	25 Sep 2020 14:22:26

US3832043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	25 Sep 2020 14:22:26

US3832043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered empty.	Alyssa-Kay Peay (b) (4)	25 Sep 2020 14:22:26

US3832043

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	25 Sep 2020 14:22:30

US3832043

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'I'	System	25 Sep 2020 14:22:30

US3832043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'Yes (Y)'	Emma Partin (b) (4)	02 Oct 2020 14:41:03

US3832043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '2 Oct 2020'	Emma Partin (b) (4)	02 Oct 2020 14:41:03

US3832043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'Clinic (Clinic)'	Emma Partin (b) (4)	02 Oct 2020 14:41:03

US3832043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:22

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'VISIT3'	System	02 Oct 2020 14:41:03

US3832043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'Yes (Y)'	Emma Partin (b) (4)	02 Oct 2020 14:41:32

US3832043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '2 Oct 2020'	Emma Partin (b) (4)	02 Oct 2020 14:41:32

US3832043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '10:18'	Emma Partin (b) (4)	02 Oct 2020 14:41:32

US3832043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered '2 Oct 2020 10:18'	System	02 Oct 2020 14:41:32

US3832043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '98.0' F	Emma Partin (b) (4)	02 Oct 2020 14:41:32

US3832043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'Oral (Oral)'	Emma Partin (b) (4)	02 Oct 2020 14:41:32

US3832043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered empty.	Emma Partin (b) (4)	02 Oct 2020 14:41:32

US3832043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '93'	Emma Partin (b) (4)	02 Oct 2020 14:41:32

US3832043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'bpm'	System	02 Oct 2020 14:41:32

US3832043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '15'	Emma Partin (b) (4)	02 Oct 2020 14:41:32

US3832043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'breaths/min'	System	02 Oct 2020 14:41:32

US3832043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '130'	Emma Partin (b) (4)	02 Oct 2020 14:41:32

US3832043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'mmHg'	System	02 Oct 2020 14:41:32

US3832043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '85'	Emma Partin (b) (4)	02 Oct 2020 14:41:32

US3832043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'mmHg'	System	02 Oct 2020 14:41:32

US3832043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02

US3832043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02

US3832043

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'Yes (Y)'	Emma Partin (b) (4)	02 Oct 2020 14:41:40

US3832043

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:22

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '2 Oct 2020'	Emma Partin (b) (4)	02 Oct 2020 14:41:40

US3832043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'Yes (Y)'	Emma Partin (b) (4)	02 Oct 2020 14:41:56

US3832043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '2 Oct 2020'	Emma Partin (b) (4)	02 Oct 2020 14:41:56

US3832043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered '10:31'	Emma Partin (b) (4)	02 Oct 2020 14:41:56

US3832043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered '2 Oct 2020 10:31'	System	02 Oct 2020 14:41:56

US3832043

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:00:56
User entered 'Yes (Y)'	Emma Partin (b) (4)	02 Oct 2020 14:42:00

US3832043

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'I'	System	02 Oct 2020 14:42:00

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	02 Aug 2020 18:16:45
User entered 'Day 64'	System	02 Aug 2020 18:16:45

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-10-06T12:07:02', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '1e26d1eb-eb05-408d-b9e0-7abbf65e6e49'	System	06 Oct 2020 16:07:14
User entered 'No (N)'	System	06 Oct 2020 16:07:14

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

Have you been exposed to someone with 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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-10-06T12:07:07', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '1e26d1eb-eb05-408d-b9e0-7abbf65e6e49'	System	06 Oct 2020 16:07:14
User entered 'No (N)'	System	06 Oct 2020 16:07:14

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-10-06T12:07:11', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '1e26d1eb-eb05-408d-b9e0-7abbf65e6e49' User entered '06 Oct 2020 12:07:11'	System	06 Oct 2020 16:07:14
	System	06 Oct 2020 16:07:14

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	02 Aug 2020 18:16:45
User entered '02 Oct 2020 00:01'	System	02 Aug 2020 18:16:45

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	02 Aug 2020 18:16:45
User entered '06 Oct 2020 23:59'	System	02 Aug 2020 18:16:45

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	02 Aug 2020 18:16:45
User entered 'Day 71'	System	02 Aug 2020 18:16:45

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-10-11T16:39:51', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'bd571259-9421-4863-bb38-d3a43799cb67'	System	11 Oct 2020 20:39:59
User entered 'No (N)'	System	11 Oct 2020 20:39:59

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

Have you been exposed to someone with 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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-10-11T16:39:54', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'bd571259-9421-4863-bb38-d3a43799cb67'	System	11 Oct 2020 20:39:59
User entered 'No (N)'	System	11 Oct 2020 20:39:59

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-10-11T16:39:57', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'bd571259-9421-4863-bb38-d3a43799cb67' User entered '11 Oct 2020 16:39:57'	System	11 Oct 2020 20:39:59
	System	11 Oct 2020 20:39:59

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	02 Aug 2020 18:16:45
User entered '09 Oct 2020 00:01'	System	02 Aug 2020 18:16:45

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	02 Aug 2020 18:16:45
User entered '13 Oct 2020 23:59'	System	02 Aug 2020 18:16:45

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	02 Aug 2020 18:16:45
User entered 'Day 78'	System	02 Aug 2020 18:16:45

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-10-19T09:37:13', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'e046e027-72d9-4201-aac1-fe13aa1bd17b' User entered 'No (N)'	System	19 Oct 2020 13:37:24
	System	19 Oct 2020 13:37:24

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

Have you been exposed to someone with 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 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-10-19T09:37:15', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'e046e027-72d9-4201-aac1-fe13aa1bd17b' User entered 'No (N)'	System	19 Oct 2020 13:37:24
	System	19 Oct 2020 13:37:24

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-10-19T09:37:19', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'e046e027-72d9-4201-aac1-fe13aa1bd17b' User entered '19 Oct 2020 09:37:19'	System	19 Oct 2020 13:37:24
	System	19 Oct 2020 13:37:24

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	02 Aug 2020 18:16:45
User entered '16 Oct 2020 00:01'	System	02 Aug 2020 18:16:45

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:23:05
Data entry locked.	System	02 Aug 2020 18:16:45
User entered '20 Oct 2020 23:59'	System	02 Aug 2020 18:16:45

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09
Data entry locked.	System	02 Aug 2020 18:16:45
User entered 'Day 92'	System	02 Aug 2020 18:16:45

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09
Data entry locked.	System	02 Aug 2020 18:16:45
User entered '30 Oct 2020 00:01'	System	02 Aug 2020 18:16:45

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09
Data entry locked.	System	02 Aug 2020 18:16:45
User entered '03 Nov 2020 23:59'	System	02 Aug 2020 18:16:45

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09
Data entry locked.	System	02 Aug 2020 18:16:45
User entered 'Day 99'	System	02 Aug 2020 18:16:45

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09
Data entry locked.	System	02 Aug 2020 18:16:45
User entered '06 Nov 2020 00:01'	System	02 Aug 2020 18:16:45

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09
Data entry locked.	System	02 Aug 2020 18:16:45
User entered '10 Nov 2020 23:59'	System	02 Aug 2020 18:16:45

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09
Data entry locked.	System	02 Aug 2020 18:16:45
User entered 'Day 106'	System	02 Aug 2020 18:16:45

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09
Data entry locked.	System	02 Aug 2020 18:16:45
User entered '13 Nov 2020 00:01'	System	02 Aug 2020 18:16:45

US3832043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:33:09
Data entry locked.	System	02 Aug 2020 18:16:45
User entered '17 Nov 2020 23:59'	System	02 Aug 2020 18:16:45

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '17 Nov 2020 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '21 Nov 2020 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '24 Nov 2020 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '28 Nov 2020 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-12-04T23:34:41', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '8dbc47f5-7c76-4676-9ddd-5802665230da' User entered 'No (N)'	System	05 Dec 2020 04:34:51
	System	05 Dec 2020 04:34:51

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-12-04T23:34:45', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '8dbc47f5-7c76-4676-9ddd-5802665230da' User entered 'No (N)'	System	05 Dec 2020 04:34:51
	System	05 Dec 2020 04:34:51

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-12-04T23:34:48', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '8dbc47f5-7c76-4676-9ddd-5802665230da' User entered '04 Dec 2020 23:34:48'	System	05 Dec 2020 04:34:51
	System	05 Dec 2020 04:34:51

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '01 Dec 2020 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '05 Dec 2020 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-12-08T11:02:19', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '378734d5-b225-4e15-baba-dbeaa98f9884' User entered 'No (N)'	System	08 Dec 2020 16:02:28
	System	08 Dec 2020 16:02:28

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-12-08T11:02:21', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '378734d5-b225-4e15-baba-dbeaa98f9884' User entered 'No (N)'	System	08 Dec 2020 16:02:28
	System	08 Dec 2020 16:02:28

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-12-08T11:02:24', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '378734d5-b225-4e15-baba-dbeaa98f9884' User entered '08 Dec 2020 11:02:24'	System	08 Dec 2020 16:02:28
	System	08 Dec 2020 16:02:28

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '08 Dec 2020 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '12 Dec 2020 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-12-17T09:22:13', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '96b0a50f-1473-49c5-9410-1eae6e18016a' User entered 'No (N)'	System	17 Dec 2020 14:22:23
	System	17 Dec 2020 14:22:23

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-12-17T09:22:17', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '96b0a50f-1473-49c5-9410-1eae6e18016a' User entered 'No (N)'	System	17 Dec 2020 14:22:23
	System	17 Dec 2020 14:22:23

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-12-17T09:22:20', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '96b0a50f-1473-49c5-9410-1eae6e18016a' User entered '17 Dec 2020 09:22:20'	System	17 Dec 2020 14:22:23
	System	17 Dec 2020 14:22:23

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '15 Dec 2020 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '19 Dec 2020 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-12-22T12:36:12', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '8aba5715-8316-4d6f-876f-abf18e4575ba' User entered 'No (N)'	System	22 Dec 2020 17:36:22
	System	22 Dec 2020 17:36:22

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-12-22T12:36:15', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '8aba5715-8316-4d6f-876f-abf18e4575ba' User entered 'No (N)'	System	22 Dec 2020 17:36:22

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-12-22T12:36:18', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '8aba5715-8316-4d6f-876f-abf18e4575ba' User entered '22 Dec 2020 12:36:18'	System	22 Dec 2020 17:36:22
	System	22 Dec 2020 17:36:22

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '22 Dec 2020 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '26 Dec 2020 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-12-29T16:29:49', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '19c26899-d65d-4391-8e95-096e3d4e7239'	System	29 Dec 2020 21:29:56
User entered 'No (N)'	System	29 Dec 2020 21:29:56

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-12-29T16:29:51', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '19c26899-d65d-4391-8e95-096e3d4e7239'	System	29 Dec 2020 21:29:56
User entered 'No (N)'	System	29 Dec 2020 21:29:56

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2020-12-29T16:29:54', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '19c26899-d65d-4391-8e95-096e3d4e7239' User entered '29 Dec 2020 16:29:54'	System	29 Dec 2020 21:29:56
	System	29 Dec 2020 21:29:56

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '29 Dec 2020 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '02 Jan 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-01-06T12:31:52', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '538a2669-2480-42e8-8cf4-bcf0387bc638' User entered 'No (N)'	System	06 Jan 2021 17:32:15
	System	06 Jan 2021 17:32:15

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-01-06T12:31:55', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '538a2669-2480-42e8-8cf4-bcf0387bc638'	System	06 Jan 2021 17:32:15
User entered 'Yes (Y)'	System	06 Jan 2021 17:32:15

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-01-06T12:32:02', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '538a2669-2480-42e8-8cf4-bcf0387bc638'	System	06 Jan 2021 17:32:15
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Jan 2021 17:32:15

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-01-06T12:32:05', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '538a2669-2480-42e8-8cf4-bcf0387bc638' User entered '06 Jan 2021 12:32:05'	System	06 Jan 2021 17:32:15
	System	06 Jan 2021 17:32:15

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '05 Jan 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '09 Jan 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '12 Jan 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '16 Jan 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-01-19T21:10:41', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '9815395a-967f-49d6-88d8-f401cb00bb56' User entered 'No (N)'	System	20 Jan 2021 02:11:13
	System	20 Jan 2021 02:11:13

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-01-19T21:10:44', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '9815395a-967f-49d6-88d8-f401cb00bb56' User entered 'No (N)'	System	20 Jan 2021 02:11:13
	System	20 Jan 2021 02:11:13

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-01-19T21:10:46', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '9815395a-967f-49d6-88d8-f401cb00bb56' User entered '19 Jan 2021 21:10:46'	System	20 Jan 2021 02:11:13
	System	20 Jan 2021 02:11:13

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '19 Jan 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '23 Jan 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '26 Jan 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '30 Jan 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '02 Feb 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '06 Feb 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '09 Feb 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '13 Feb 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-02-16T13:50:42', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'bbb72b86-e044-401b-aa38-c863ffe4f9b6'	System	16 Feb 2021 18:50:49
User entered 'No (N)'	System	16 Feb 2021 18:50:49

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-02-16T13:50:45', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'bbb72b86-e044-401b-aa38-c863ffe4f9b6'	System	16 Feb 2021 18:50:49
User entered 'No (N)'	System	16 Feb 2021 18:50:49

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-02-16T13:50:47', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'bbb72b86-e044-401b-aa38-c863ffe4f9b6' User entered '16 Feb 2021 13:50:47'	System	16 Feb 2021 18:50:49
	System	16 Feb 2021 18:50:49

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '16 Feb 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '20 Feb 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-02-23T21:17:25-05:00', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '2699b81b-22d0-400b-9369-8e97cc873ad0'	System	24 Feb 2021 02:24:24
User entered 'No (N)'	System	24 Feb 2021 02:24:24

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-02-23T21:17:27-05:00', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '2699b81b-22d0-400b-9369-8e97cc873ad0'	System	24 Feb 2021 02:24:24
User entered 'No (N)'	System	24 Feb 2021 02:24:24

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-02-23T21:17:29-05:00', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '2699b81b-22d0-400b-9369-8e97cc873ad0'	System	24 Feb 2021 02:24:24
User entered '24 Feb 2021 02:17:29'	System	24 Feb 2021 02:24:24

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '23 Feb 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '27 Feb 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '02 Mar 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '06 Mar 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-03-09T11:20:42-05:00', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '473f4116-23a3-4aec-8c6c-57d36304a7ea' User entered 'No (N)'	System	09 Mar 2021 16:20:50
	System	09 Mar 2021 16:20:50

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-03-09T11:20:44-05:00', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '473f4116-23a3-4aec-8c6c-57d36304a7ea'	System	09 Mar 2021 16:20:50
User entered 'No (N)'	System	09 Mar 2021 16:20:50

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-03-09T11:20:47-05:00', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '473f4116-23a3-4aec-8c6c-57d36304a7ea' User entered '09 Mar 2021 11:20:47'	System	09 Mar 2021 16:20:50
	System	09 Mar 2021 16:20:50

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '09 Mar 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '13 Mar 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-03-17T15:02:05-04:00', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '28a9dfef-4b43-4234-9e98-4644d8bd3c2d'	System	17 Mar 2021 19:02:53
User entered 'No (N)'	System	17 Mar 2021 19:02:53

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-03-17T15:02:10-04:00', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '28a9dfef-4b43-4234-9e98-4644d8bd3c2d'	System	17 Mar 2021 19:02:53
User entered 'No (N)'	System	17 Mar 2021 19:02:53

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-03-17T15:02:13-04:00', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '28a9dfef-4b43-4234-9e98-4644d8bd3c2d' User entered '17 Mar 2021 15:02:13'	System	17 Mar 2021 19:02:53
	System	17 Mar 2021 19:02:53

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '16 Mar 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '20 Mar 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-03-23T09:12:26-04:00', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'e5d9ae7b-5521-4a66-9c6d-0c65c3f55ce7'	System	23 Mar 2021 13:12:38
User entered 'No (N)'	System	23 Mar 2021 13:12:38

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-03-23T09:12:28-04:00', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'e5d9ae7b-5521-4a66-9c6d-0c65c3f55ce7'	System	23 Mar 2021 13:12:38
User entered 'No (N)'	System	23 Mar 2021 13:12:38

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-03-23T09:12:31-04:00', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'e5d9ae7b-5521-4a66-9c6d-0c65c3f55ce7'	System	23 Mar 2021 13:12:38
User entered '23 Mar 2021 09:12:31'	System	23 Mar 2021 13:12:38

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '23 Mar 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '27 Mar 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-03-30T22:44:29-04:00', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '95ce2ea1-78e1-430d-815b-525ee738de24' User entered 'No (N)'	System	31 Mar 2021 02:44:39
	System	31 Mar 2021 02:44:39

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-03-30T22:44:31-04:00', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '95ce2ea1-78e1-430d-815b-525ee738de24'	System	31 Mar 2021 02:44:39
User entered 'No (N)'	System	31 Mar 2021 02:44:39

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-03-30T22:44:35-04:00', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '95ce2ea1-78e1-430d-815b-525ee738de24' User entered '30 Mar 2021 22:44:35'	System	31 Mar 2021 02:44:39

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '30 Mar 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '03 Apr 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-04-08T20:12:54-05:00', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'e287e612-efd5-4909-ba4a-5df1bf215d9f' User entered 'No (N)'	System	09 Apr 2021 01:16:42
	System	09 Apr 2021 01:16:42

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-04-08T20:12:57-05:00', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'e287e612-efd5-4909-ba4a-5df1bf215d9f' User entered 'No (N)'	System	09 Apr 2021 01:16:42

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-04-08T20:13:01-05:00', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: 'e287e612-efd5-4909-ba4a-5df1bf215d9f' User entered '08 Apr 2021 20:13:01'	System	09 Apr 2021 01:16:42
	System	09 Apr 2021 01:16:42

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '06 Apr 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '10 Apr 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '13 Apr 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '17 Apr 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-04-20T16:26:56-04:00', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '12b87bcb-3eda-482b-9ce1-1315a7687abb' User entered 'No (N)'	System	20 Apr 2021 20:27:07
	System	20 Apr 2021 20:27:07

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-04-20T16:26:58-04:00', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '12b87bcb-3eda-482b-9ce1-1315a7687abb'	System	20 Apr 2021 20:27:07
User entered 'No (N)'	System	20 Apr 2021 20:27:07

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-04-20T16:27:01-04:00', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '12b87bcb-3eda-482b-9ce1-1315a7687abb'	System	20 Apr 2021 20:27:07
User entered '20 Apr 2021 16:27:01'	System	20 Apr 2021 20:27:07

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '20 Apr 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '24 Apr 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-04-30T20:46:18-04:00', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '0d535c42-5a22-4b15-bdd8-25b3eaeae4f'	System	01 May 2021 00:46:27
User entered 'No (N)'	System	01 May 2021 00:46:27

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-04-30T20:46:20-04:00', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '0d535c42-5a22-4b15-bdd8-25b3eaeae4f'	System	01 May 2021 00:46:27
User entered 'No (N)'	System	01 May 2021 00:46:27

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-04-30T20:46:23-04:00', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '0d535c42-5a22-4b15-bdd8-25b3eaeae4f'	System	01 May 2021 00:46:27
User entered '30 Apr 2021 20:46:23'	System	01 May 2021 00:46:27

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '27 Apr 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '01 May 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '04 May 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '08 May 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '11 May 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '15 May 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '18 May 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '22 May 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '25 May 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '29 May 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '01 Jun 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '05 Jun 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '08 Jun 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '12 Jun 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '15 Jun 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '19 Jun 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '22 Jun 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '26 Jun 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '29 Jun 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '03 Jul 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '06 Jul 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '10 Jul 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '13 Jul 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '17 Jul 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '20 Jul 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '24 Jul 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '27 Jul 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '31 Jul 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '03 Aug 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '07 Aug 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '10 Aug 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '14 Aug 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '17 Aug 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '21 Aug 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '24 Aug 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '28 Aug 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '31 Aug 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '04 Sep 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '07 Sep 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '11 Sep 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '14 Sep 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '18 Sep 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '21 Sep 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '25 Sep 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '28 Sep 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '02 Oct 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '05 Oct 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '09 Oct 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '12 Oct 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '16 Oct 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '19 Oct 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '23 Oct 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '26 Oct 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '30 Oct 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '02 Nov 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '06 Nov 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '09 Nov 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '13 Nov 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '16 Nov 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '20 Nov 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '23 Nov 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '27 Nov 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '30 Nov 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '04 Dec 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '07 Dec 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '11 Dec 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '14 Dec 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '18 Dec 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '21 Dec 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '25 Dec 2021 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '28 Dec 2021 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '01 Jan 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '04 Jan 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '08 Jan 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '11 Jan 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '15 Jan 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '18 Jan 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '22 Jan 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '25 Jan 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '29 Jan 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '01 Feb 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '05 Feb 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '08 Feb 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '12 Feb 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '15 Feb 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '19 Feb 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '22 Feb 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '26 Feb 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '01 Mar 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '05 Mar 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '08 Mar 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '12 Mar 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '15 Mar 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '19 Mar 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '22 Mar 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '26 Mar 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '29 Mar 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '02 Apr 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '05 Apr 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '09 Apr 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '12 Apr 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '16 Apr 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '19 Apr 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '23 Apr 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '26 Apr 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '30 Apr 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '03 May 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '07 May 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '10 May 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '14 May 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '17 May 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '21 May 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '24 May 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '28 May 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '31 May 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '04 Jun 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '07 Jun 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '11 Jun 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '14 Jun 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '18 Jun 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '21 Jun 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '25 Jun 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '28 Jun 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '02 Jul 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '05 Jul 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '09 Jul 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '12 Jul 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '16 Jul 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '19 Jul 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '23 Jul 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '26 Jul 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '30 Jul 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '02 Aug 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '06 Aug 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '09 Aug 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '13 Aug 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '16 Aug 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '20 Aug 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '23 Aug 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '27 Aug 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '30 Aug 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '03 Sep 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '06 Sep 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '10 Sep 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '13 Sep 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '17 Sep 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '20 Sep 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '24 Sep 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '27 Sep 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '01 Oct 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '04 Oct 2022 00:01'	System	19 Nov 2020 11:33:09

US3832043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:33:09
Amendment Manager: User entered '08 Oct 2022 23:59'	System	19 Nov 2020 11:33:09

US3832043

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:00:22

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-03-01T10:05:12-05:00', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '548c28f1-7da1-4c8d-9e9b-3480e04c638a' User entered 'No (N)'	System	01 Mar 2021 15:05:20
	System	01 Mar 2021 15:05:20

US3832043

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:00:22

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:34:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95A15A84-78B1-4EF0-852C-674DA2426A43)', Time: '2021-03-01T10:05:17-05:00', User OID: 'PatientReportedOutcome (US3832043)', ODM File OID: '548c28f1-7da1-4c8d-9e9b-3480e04c638a' User entered '01 Mar 2021 10:05:17'	System	01 Mar 2021 15:05:20
	System	01 Mar 2021 15:05:20

US3832043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4) (b) (4)	30 Oct 2020 14:16:03

US3832043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered '30 Oct 2020'	Alyssa-Kay Peay (b) (4)	30 Oct 2020 14:16:03

US3832043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alyssa-Kay Peay (b) (4)	30 Oct 2020 14:16:03

US3832043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered empty.	Alyssa-Kay Peay (b) (4)	30 Oct 2020 14:16:03

US3832043

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	30 Oct 2020 14:16:08

US3832043

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:02
User entered 'I'	System	30 Oct 2020 14:16:08

US3832043

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:44:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	10 Dec 2020 19:48:54

US3832043

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:44:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered '03 Dec 2020'	Danyel Johnson (b) (4)	10 Dec 2020 19:48:54

US3832043

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:44:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered 'Contact Made (CONTACT MADE)'	Danyel Johnson (b) (4)	10 Dec 2020 19:48:54

US3832043

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:44:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered empty.	Danyel Johnson (b) (4)	10 Dec 2020 19:48:54

US3832043

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:44:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	10 Dec 2020 19:50:16

US3832043

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:44:58
User entered 'I'	System	10 Dec 2020 19:50:16

US3832043

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:44:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	05 Jan 2021 20:04:32

US3832043

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:44:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	05 Jan 2021 20:04:54
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	05 Jan 2021 20:04:54
User entered '5 Jan 2021' reason for change: Data Entry Error	Rodolfo Barrera (b) (4)	05 Jan 2021 20:04:54
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	05 Jan 2021 20:04:32
User entered '29 Dec 2020'	Rodolfo Barrera (b) (4)	05 Jan 2021 20:04:32

US3832043

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:44:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered 'Contact Made (CONTACT MADE)'	Rodolfo Barrera (b) (4)	05 Jan 2021 20:04:32

US3832043

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:44:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered empty.	Rodolfo Barrera (b) (4)	05 Jan 2021 20:04:32

US3832043

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:44:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	05 Jan 2021 20:05:01

US3832043

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:44:58
User entered 'I'	System	05 Jan 2021 20:05:01

US3832043

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:44:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	02 Feb 2021 17:23:46

US3832043

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:44:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered '2 Feb 2021'	Rodolfo Barrera (b) (4)	02 Feb 2021 17:23:46

US3832043

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:44:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered 'Contact Made (CONTACT MADE)'	Rodolfo Barrera (b) (4)	02 Feb 2021 17:23:46

US3832043

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:44:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered empty.	Rodolfo Barrera (b) (4)	02 Feb 2021 17:23:46

US3832043

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:44:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	02 Feb 2021 17:23:55

US3832043

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:44:58
User entered 'I'	System	02 Feb 2021 17:23:55

US3832043

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:44:48
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:01:31
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	15 Mar 2021 18:02:02

US3832043

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:44:48
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:01:31
User entered '9 Mar 2021'	Rodolfo Barrera (b) (4)	15 Mar 2021 18:02:02

US3832043

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:44:48
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:01:31
User entered 'Clinic (Clinic)'	Rodolfo Barrera (b) (4)	15 Mar 2021 18:02:02

US3832043

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:22

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:44:48
User entered 'VISIT4'	System	15 Mar 2021 18:02:02

US3832043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:44:48
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:01:31
User entered 'No (N)'	(b) (4)	
	Danyel Johnson (b) (4)	31 Mar 2021 02:41:11
	(b) (4)	

US3832043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:44:48
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:01:31
User entered empty.	Danyel Johnson (b) (4)	31 Mar 2021 02:41:11

US3832043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:44:48
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:01:31
User entered empty.	Danyel Johnson (b) (4)	31 Mar 2021 02:41:11

US3832043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:44:48
User entered empty.	System	31 Mar 2021 02:41:11

US3832043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:44:48
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:01:31
User entered empty.	(b) (4)	
	Danyel Johnson (b) (4)	31 Mar 2021 02:41:11
	(b) (4)	

US3832043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:44:48
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:01:31
User entered empty.	Danyel Johnson (b) (4)	31 Mar 2021 02:41:11

US3832043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:44:48
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:01:31
User entered empty.	Danyel Johnson (b) (4)	31 Mar 2021 02:41:11

US3832043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:44:48
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:01:31
User entered empty.	Danyel Johnson (b) (4)	31 Mar 2021 02:41:11

US3832043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:44:48
User entered empty.	System	31 Mar 2021 02:41:11

US3832043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:44:48
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:01:31
User entered empty.	(b) (4)	
	Danyel Johnson (b) (4)	31 Mar 2021 02:41:11
	(b) (4)	

US3832043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:44:48
User entered empty.	System	31 Mar 2021 02:41:11

US3832043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:44:48
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:01:31
User entered empty.	Danyel Johnson (b) (4)	31 Mar 2021 02:41:11

US3832043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:44:48
User entered empty.	System	31 Mar 2021 02:41:11

US3832043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:44:48
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:01:31
User entered empty.	Danyel Johnson (b) (4)	31 Mar 2021 02:41:11

US3832043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:44:48
User entered empty.	System	31 Mar 2021 02:41:11

US3832043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:44:48

US3832043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:22

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:44:48

US3832043

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:44:48
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:01:31
User entered 'No (N)'	Rodolfo Barrera (b) (4)	15 Mar 2021 18:02:08

US3832043

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:22

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:44:48
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:01:31
User entered empty.	Rodolfo Barrera (b) (4)	15 Mar 2021 18:02:08

US3832043

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:44:48
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:01:31
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	15 Mar 2021 18:02:26

US3832043

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:44:48
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:01:31
User entered '9 Mar 2021'	Rodolfo Barrera (b) (4)	15 Mar 2021 18:02:26

US3832043

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:44:48
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:01:31
User entered '13:30'	Rodolfo Barrera (b) (4)	15 Mar 2021 18:02:26

US3832043

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:44:48
User entered '9 Mar 2021 13:30'	System	15 Mar 2021 18:02:26

US3832043

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:44:48
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:01:31
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	15 Mar 2021 18:03:00

US3832043

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:44:48
User entered 'I'	System	15 Mar 2021 18:03:00

US3832043

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:07
	(b) (4)	
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	13 Apr 2021 20:57:50
	(b) (4)	

US3832043

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:07
	(b) (4)	
User entered '30 Mar 2021'	Rodolfo Barrera (b) (4)	13 Apr 2021 20:57:50
	(b) (4)	

US3832043

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Rodolfo Barrera (b) (4)	13 Apr 2021 20:57:50

US3832043

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:07
	(b) (4)	
User entered empty.	Rodolfo Barrera (b) (4)	13 Apr 2021 20:57:50
	(b) (4)	

US3832043

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:07
	(b) (4)	
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	13 Apr 2021 20:57:56
	(b) (4)	

US3832043

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 20:57:56

US3832043

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:37
	(b) (4)	
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	29 Apr 2021 16:15:25
	(b) (4)	

US3832043

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:37
	(b) (4)	
User entered '29 Apr 2021'	Rodolfo Barrera (b) (4)	29 Apr 2021 16:15:25
	(b) (4)	

US3832043

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Rodolfo Barrera (b) (4)	29 Apr 2021 16:15:25

US3832043

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:37
	(b) (4)	
User entered empty.	Rodolfo Barrera (b) (4)	29 Apr 2021 16:15:25
	(b) (4)	

US3832043

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:37
	(b) (4)	
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	29 Apr 2021 16:15:30
	(b) (4)	

US3832043

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 16:15:30

US3832043

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

Form: Visit Date

Generated On: 10 Jun 2021 10:00:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered 'Yes (Y)'	Emma Partin (b) (4)	19 Jan 2021 19:19:35

US3832043

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

Form: Visit Date

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered '19 Jan 2021'	Emma Partin (b) (4)	19 Jan 2021 19:19:35

US3832043

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

Form: Visit Date

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered 'Clinic (Clinic)'	Emma Partin (b) (4)	19 Jan 2021 19:19:35

US3832043

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

Form: Visit Date

Generated On: 10 Jun 2021 10:00:22

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 19:19:35

US3832043

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

Form: Unblinding

Generated On: 10 Jun 2021 10:00:22

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered '19 Jan 2021'	Emma Partin (b) (4)	19 Jan 2021 19:20:15

US3832043

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

Form: Unblinding

Generated On: 10 Jun 2021 10:00:22

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:01:31
User entered '0'	Rodolfo Barrera (b) (4)	08 Apr 2021 19:54:53
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:10:02

US3832043

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

Form: Unblinding

Generated On: 10 Jun 2021 10:00:22

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered 'Yes (Y)'	Emma Partin (b) (4)	19 Jan 2021 19:20:15

US3832043

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

Form: Unblinding

Generated On: 10 Jun 2021 10:00:22

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Gowdhami Mohan (b) (4)	15 Apr 2021 18:51:32 12 Apr 2021 23:01:31
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'Updated.' (Site from DM).	Rodolfo Barrera (b) (4) (b) (4)	08 Apr 2021 19:55:00
User entered 'Amendment 6 or later (Amendment 6 or later)'	Rodolfo Barrera (b) (4) (b) (4)	08 Apr 2021 19:54:53
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM). Amendment Manager inserted this DataPoint.	(b) (4), (b) (6) System	08 Apr 2021 15:42:52 06 Mar 2021 11:10:02

US3832043

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

Form: Unblinding

Generated On: 10 Jun 2021 10:00:22

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered '19 Jan 2021'	Emma Partin (b) (4)	19 Jan 2021 19:20:15

US3832043

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

Form: Unblinding

Generated On: 10 Jun 2021 10:00:22

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered 'mRNA-1273 (mRNA-1273)'	Emma Partin (b) (4)	19 Jan 2021 19:20:15

US3832043

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

Form: Unblinding

Generated On: 10 Jun 2021 10:00:22

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 05:59:54
User entered 'mRNA-1273 (mRNA-1273)'	Emma Partin (b) (4)	19 Jan 2021 19:20:15
	(b) (4)	

US3832043

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

Form: Unblinding

Generated On: 10 Jun 2021 10:00:22

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 05:59:54
User entered 'mRNA-1273 (mRNA-1273)'	Emma Partin (b) (4)	19 Jan 2021 19:20:15
	(b) (4)	

US3832043

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

Form: Unblinding

Generated On: 10 Jun 2021 10:00:22

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered 'No (N)'	Emma Partin (b) (4)	19 Jan 2021 19:20:15

US3832043

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

Form: Unblinding

Generated On: 10 Jun 2021 10:00:22

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User entered empty.	System	19 Jan 2021 19:20:15

US3832043

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

Form: Unblinding

Generated On: 10 Jun 2021 10:00:22

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User entered empty.	System	19 Jan 2021 19:20:15

US3832043

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered 'Yes (Y)'	Emma Partin (b) (4)	19 Jan 2021 19:19:48

US3832043

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:22

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered '19 Jan 2021'	Emma Partin (b) (4)	19 Jan 2021 19:19:48

US3832043

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered '14:05'	Emma Partin (b) (4)	19 Jan 2021 19:19:48

US3832043

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User entered '19 Jan 2021 14:05'	System	19 Jan 2021 19:19:48

US3832043

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:00:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered 'Yes (Y)'	Emma Partin (b) (4)	19 Jan 2021 19:19:58

US3832043

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:00:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered '19 Jan 2021'	Emma Partin (b) (4)	19 Jan 2021 19:19:58

US3832043

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User entered '14:00'	Emma Partin (b) (4)	19 Jan 2021 19:19:58

US3832043

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:40
User entered '19 Jan 2021 14:00'	System	19 Jan 2021 19:19:58

US3832043

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:00:22

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:42
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:28:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 19:33:49

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:28:34
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 19:53:46
User entered	System	07 Sep 2020 19:53:34
'USA-US100-2020-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	07 Sep 2020 19:53:34

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:34
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Infections NEC, PT: Toxic shock syndrome, LLT: Toxic shock syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 10:56:31
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 10:56:31
Data point term sent to Coder	System	30 Sep 2020 22:29:35
Coding entries removed.	(b) (4), (b) (6)	30 Sep 2020 22:29:14
User entered 'SUSPECTED TOXIC SHOCK SYNDROME' reason for change: New Information	(b) (4), (b) (6)	30 Sep 2020 22:29:14
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Bacterial infection, LLT: Bacterial infection - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 07:25:46
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 07:25:46
Data point term sent to Coder	System	04 Sep 2020 19:36:50
User entered 'Suspected Bacterial Infection'	(b) (4), (b) (6)	04 Sep 2020 19:36:02

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 19:36:02

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:34
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 19:36:02

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:28:34
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 19:36:02

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:34
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 19:13:52
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	04 Sep 2020 19:36:02
User entered '23 Aug 2020'	(b) (4), (b) (6)	04 Sep 2020 19:36:02

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:34
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 19:36:02

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 19:36:02

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:34
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 19:36:02

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:34
User entered '25 Aug 2020' reason for change: New Information	(b) (4), (b) (6)	30 Sep 2020 22:29:14
User entered '30 Aug 2020'	(b) (4), (b) (6)	04 Sep 2020 19:36:02

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:28:34
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 19:36:02

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 19:36:02

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:34
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	04 Sep 2020 19:36:02

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 19:36:02

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:28:34
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 19:36:02

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:28:34
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 19:36:02

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:28:34
User entered 'I'	(b) (4), (b) (6)	04 Sep 2020 19:36:02

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:34
User entered '23 Aug 2020'	(b) (4), (b) (6)	04 Sep 2020 19:36:02

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:34
User entered '25 Aug 2020'	(b) (4), (b) (6)	04 Sep 2020 19:36:02

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:28:34
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 19:36:02

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:28:34
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 19:36:02

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:28:34
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 19:36:02

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:28:34
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 19:36:02

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:28:34
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 19:36:02

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:34
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	04 Sep 2020 19:36:02

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:34
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	04 Sep 2020 19:36:02

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:34
User entered 'None (NONE)'	(b) (4), (b) (6)	04 Sep 2020 19:36:02

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:28:34
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 19:36:02

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:28:34
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, there is no corresponding ConMed record that match this AE during this time frame. Please update to record the corresponding ConMed as appropriate or update Other Action Taken. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 14:09:11
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, there is no corresponding ConMed record that match this AE during this time frame. Please update to record the corresponding ConMed as appropriate or update Other Action Taken. Otherwise, clarify.' answered with 'ConMed page updated.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 22:23:23
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, there is no corresponding ConMed record that match this AE during this time frame. Please update to record the corresponding ConMed as appropriate or update Other Action Taken. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Sep 2020 16:27:00
User entered 'I'	(b) (4), (b) (6)	04 Sep 2020 19:36:02

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:28:34
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 19:36:02

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	04 Sep 2020 19:36:02

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:34
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 19:36:02

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:34
User closed query 'PV Query: Urine and bacterial cultures were reported as negative, and imaging was reported as normal. Please provide the clinical and diagnostic evidence supporting diagnosis of toxic shock syndrome.' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 16:02:25
Query 'PV Query: Urine and bacterial cultures were reported as negative, and imaging was reported as normal. Please provide the clinical and diagnostic evidence supporting diagnosis of toxic shock syndrome.' answered with 'The subject was hospitalized and treated for "suspected" toxic shock syndrome. The discharge summary did not provide an alternative diagnosis.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 21:40:25
User closed query 'Per DM CLR: SAE Narrative indicates that the subject had elevated heart rate, fever and abdominal pain. However, these conditions were not noted on the AE page. Please review and update to record the corresponding AE if applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 07:54:24
User opened query 'PV Query: Urine and bacterial cultures were reported as negative, and imaging was reported as normal. Please provide the clinical and diagnostic evidence supporting diagnosis of toxic shock syndrome.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 14:10:57
User closed query 'Per DM CLR: SAE Narrative indicates that Chest X-Ray and CT Scan were performed. However, there are no corresponding Concomitant Procedure record that match these procedures. Please update to record the corresponding procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 14:10:50
User closed query 'Per DM CLR: SAE Narrative indicates that the subject was treated with IV Antibiotics and Home medication of Augmentin. However, there are no corresponding ConMed record that match these medications. Please update to record accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 14:10:40

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the subject's vital signs at the time of the event.' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 16:59:25
User closed query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 16:59:22
User closed query 'PV Query: Please provide laboratory/diagnostic test performed in evaluation of possible infection (i.e. CBC with differential, ESR, CRP, urine culture, etc) including units and reference ranges, when applicable ' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 16:59:15
User closed query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 16:59:12
User closed query 'PV Query: It was reported that the subject had fever. Please provide initial temperature and max temperature experienced, along with date(s) of occurrence.' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 16:59:09
Query 'Per DM CLR: SAE Narrative indicates that Chest X-Ray and CT Scan were performed. However, there are no corresponding Concomitant Procedure record that match these procedures. Please update to record the corresponding procedures as appropriate. Otherwise, clarify.' answered with 'Concomitant procedures eCRF updated' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 22:34:25
Query 'Per DM CLR: SAE Narrative indicates that the subject was treated with IV Antibiotics and Home medication of Augmentin. However, there are no corresponding ConMed record that match these medications. Please update to record accordingly. Otherwise, clarify.' answered with 'medications added to con med eCRF' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 22:31:27

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative indicates that the subject had elevated heart rate, fever and abdominal pain. However, these conditions were not noted on the AE page. Please review and update to record the corresponding AE if applicable. Otherwise, clarify.' answered with 'These conditions are considered symptoms directly related to event of suspected toxic shock syndrome. Per PI, these conditions do not constitute separate AEs.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 22:31:13
Query 'PV Query: Please provide the subject's vital signs at the time of the event.' answered with 'Vital signs added to narrative' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 22:30:30
Query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' answered with 'treatment added to narrative and con med eCRF updated.' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 22:30:22
Query 'PV Query: Please provide laboratory/diagnostic test performed in evaluation of possible infection (i.e. CBC with differential, ESR, CRP, urine culture, etc) including units and reference ranges, when applicable ' answered with 'relevant lab tests added to narrative.' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 22:30:03
Query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' answered with 'Subject was not tested for COVID-19' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 22:29:46
Query 'PV Query: It was reported that the subject had fever. Please provide initial temperature and max temperature experienced, along with date(s) of occurrence.' answered with 'Temperature at admission and discharge added to narrative.' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 22:29:35

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

[Narrative](#)

Audit	User	Time (GMT)
User entered 'UPON ARRIVAL AT DAY 29 VISIT, SUBJECT REPORTED BEING ADMITTED TO HOSPITAL FOR SUSPECTED BACTERIAL INFECTION FROM 23AUG2020 - 25AUG2020. SUBJET REPORTS PRESENTING WITH ELEVATED HEART RATE, FEVER AND MODERATE ABDOMINAL PAIN. SUBJECT STATES A CHEST X-RAY AND CT SCAN OF THE ABDOMEN WERE PERFORMED. BOTH WERE INSIGNIFICANT PER SUBJECT REPORT. SUBJECT STATES SHE WAS ADMITTED FOR OBSERVATION AND REPORTED BEING TREATED WITH IV ANTIBIOTICS DURING ADMISSION. SHE REPORTS BEING GIVEN A 5 DAY COURSE OF AUGMENTIN UPON DISCHARGE. BACTERIAL CULTURES WERE NEGATIVE FOR SEPSIS PER SUBJECT REPORT. MEDICAL RECORDS WERE REQUESTED AND WILL UPDATE WHEN RECORDS RECEIVED AND REVIEWED. FOLLOW-UP #1: Medical records from hospitalization reviewed and discussed with subject. Subject presented to hospital with symptoms of malaise, chills, nausea, abdominal pain and fever. Vital signs on admission (23/Aug/2020): Temp 100.3F; Pulse 143; Resp. 18; BP 155/98; SpO2 97%. Subject admitted due to suspected Toxic Shock Syndrome or Sepsis. Subject had elevated WBC (15.92 K/uL; reference 3.50 - 10.80 K/uL) and Lactate (2.39 mmol/L; reference 0.40 - 2.00 mmol/L) upon admission. Chest X-ray and Abdominal CT scan were performed with no significant findings. Blood and urine cultures performed throughout admission were negative. Subject treated with IV Vancomycin, Zosyn and Clindamycin during hospitalization. Subject given IV Pepcid for GI Prophylaxis. Subject noted to have a Urinary Tract Infection and was provided course of Augmentin upon discharge. Avg. Vital Signs over last 24hrs of admission were: Temp. 98.0F; Pulse 79; Resp. 18; BP 125/74; SpO2 97%. Subject noted to be in stable condition and feeling well upon discharge from	(b) (4), (b) (6)	30 Sep 2020 22:29:14

PRODUCTION RELEASE (v12.003
EAB) (1725)

1702 of 2006

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

[Narrative](#)

Audit	User	Time (GMT)
hospital, and has recovered from suspected Toxic Shock Syndrome and Urinary Tract Infection.'		
reason for change: New Information		
User opened query 'Per DM CLR: SAE Narrative indicates that the subject was treated with IV Antibiotics and Home medication of Augmentin. However, there are no corresponding ConMed record that match these medications. Please update to record accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Sep 2020 16:28:22
User opened query 'Per DM CLR: SAE Narrative indicates that Chest X-Ray and CT Scan were performed. However, there are no corresponding Concomitant Procedure record that match these procedures. Please update to record the corresponding procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Sep 2020 16:28:10
User opened query 'Per DM CLR: SAE Narrative indicates that the subject had elevated heart rate, fever and abdominal pain. However, these conditions were not noted on the AE page. Please review and update to record the corresponding AE if applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Sep 2020 16:28:00
User opened query 'PV Query: Please provide the subject's vital signs at the time of the event.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 16:21:31
User opened query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 16:21:14
User opened query 'PV Query: Please provide laboratory/diagnostic test performed in evaluation of possible infection (i.e. CBC with differential, ESR, CRP, urine culture, etc) including units and reference ranges, when applicable ' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 16:21:03
User opened query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 16:20:50
User opened query 'PV Query: It was reported that the subject had fever. Please provide initial temperature and max temperature experienced, along with date(s) of occurrence.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 16:20:38

PRODUCTION RELEASE (v12.003
EAB) (1725)

1703 of 2006

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Upon arrival at Day 29 visit, subject reported being admitted to hospital for suspected bacterial infection from 23Aug2020 - 25Aug2020. Subjet reports presenting with elevated heart rate, fever and moderate abdominal pain. Subject states a chest x-ray and CT scan of the abdomen were performed. Both were insignificant per subject report. Subject states she was admitted for observation and reported being treated with IV antibiotics during admission. She reports being given a 5 day course of augmentin upon discharge. Bacterial cultures were negative for sepsis per subject report. Medical records were requested and will update when records received and reviewed.'	(b) (4), (b) (6)	04 Sep 2020 19:36:02

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 19:36:02

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Sep 2020 19:36:02

US3832043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:22

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Sep 2020 19:36:02

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:31:38
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 22:00:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 22:00:43
Data point term sent to Coder	System	30 Sep 2020 21:59:50
User entered 'Urinary Tract Infection'	(b) (4), (b) (6)	30 Sep 2020 21:59:36

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:31:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 21:59:36

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:31:38
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 21:59:36

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:31:38
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 21:59:36

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:31:38
User entered '23 Aug 2020'	(b) (4), (b) (6)	30 Sep 2020 21:59:36

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:31:38
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:59:36

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48
User entered empty.	System	30 Sep 2020 21:59:36

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:31:38
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 21:59:36

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:31:38
User entered '30 Aug 2020'	(b) (4), (b) (6)	30 Sep 2020 21:59:36

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:31:38
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:59:36

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48
User entered empty.	System	30 Sep 2020 21:59:36

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:31:38
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	30 Sep 2020 21:59:36

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:31:38
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 21:59:36

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:31:38
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 21:59:36

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:31:38
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 21:59:36

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:31:38
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 21:59:36

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:31:38
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:59:36

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:31:38
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:59:36

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:31:38
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:59:36

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:31:38
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:59:36

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:31:38
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 21:59:36

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:31:38
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 21:59:36

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:31:38
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 21:59:36

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:31:38
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	30 Sep 2020 21:59:36

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:31:38
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	30 Sep 2020 21:59:36

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:31:38
User entered 'None (NONE)'	(b) (4), (b) (6)	30 Sep 2020 21:59:36

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:31:38
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 21:59:36

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:31:38
User entered 'l'	(b) (4), (b) (6)	30 Sep 2020 21:59:36

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:31:38
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 21:59:36

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:31:38
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	30 Sep 2020 21:59:36

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:31:38
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:59:36

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:31:38
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:59:36

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48
User entered '0'	System	30 Sep 2020 21:59:36

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48
User entered '1'	System	30 Sep 2020 21:59:36

US3832043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:22

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:45:48

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:22

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	20 Apr 2021 19:29:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 19:29:29
Data point term sent to Coder	System	20 Apr 2021 19:28:10
User entered 'Worsening of Seasonal Allergies'	Ashten Sheriff (b) (4)	20 Apr 2021 19:27:53
	(b) (4)	

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	20 Apr 2021 19:27:53
	(b) (4)	

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered 'No (N)'	Ashten Sheriff (b) (4)	20 Apr 2021 19:27:53
	(b) (4)	

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered 'No (N)'	Ashten Sheriff (b) (4)	20 Apr 2021 19:27:53
	(b) (4)	

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered '14 Apr 2021'	Ashten Sheriff (b) (4)	20 Apr 2021 19:27:53
	(b) (4)	

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:22

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4)	20 Apr 2021 19:28:11
User entered empty; reason for change Data Entry Error	Ashten Sheriff (b) (4)	20 Apr 2021 19:28:11
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	20 Apr 2021 19:27:53
User entered '00:00'	Ashten Sheriff (b) (4)	20 Apr 2021 19:27:53
	(b) (4)	

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:22

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 19:28:11
User entered '14 Apr 2021 00:00'	System	20 Apr 2021 19:27:53

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:22

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	20 Apr 2021 19:27:53
	(b) (4)	

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:22

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered empty.	Ashten Sheriff (b) (4)	20 Apr 2021 19:27:53
	(b) (4)	

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:22

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered empty.	Ashten Sheriff (b) (4)	20 Apr 2021 19:27:53
	(b) (4)	

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:22

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 19:27:53

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:22

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Ashten Sheriff (b) (4)	20 Apr 2021 19:27:53

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered 'No (N)'	Ashten Sheriff (b) (4)	20 Apr 2021 19:27:53
	(b) (4)	

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:22

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered '0'	Ashten Sheriff (b) (4)	20 Apr 2021 19:27:53
	(b) (4)	

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:22

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered '0'	Ashten Sheriff (b) (4)	20 Apr 2021 19:27:53
	(b) (4)	

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered '0'	Ashten Sheriff (b) (4)	20 Apr 2021 19:27:53
	(b) (4)	

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:22

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered empty.	Ashten Sheriff (b) (4)	20 Apr 2021 19:27:53
	(b) (4)	

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:22

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered empty.	Ashten Sheriff (b) (4)	20 Apr 2021 19:27:53
	(b) (4)	

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:22

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered empty.	Ashten Sheriff (b) (4)	20 Apr 2021 19:27:53
	(b) (4)	

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:22

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
User entered empty.	(b) (4) Ashten Sheriff (b) (4)	20 Apr 2021 19:27:53
	(b) (4)	

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered '0'	Ashten Sheriff (b) (4)	20 Apr 2021 19:27:53
	(b) (4)	

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered '0'	Ashten Sheriff (b) (4)	20 Apr 2021 19:27:53
	(b) (4)	

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:22

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered '0'	Ashten Sheriff (b) (4)	20 Apr 2021 19:27:53
	(b) (4)	

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
User entered 'Not Related (NOT RELATED)'	(b) (4) Ashten Sheriff (b) (4)	20 Apr 2021 19:27:53
	(b) (4)	

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Ashten Sheriff (b) (4)	20 Apr 2021 19:27:53

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:22

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Ashten Sheriff (b) (4)	20 Apr 2021 19:27:53

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:22

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered '0'	Ashten Sheriff (b) (4)	20 Apr 2021 19:27:53
	(b) (4)	

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered '1'	Ashten Sheriff (b) (4)	20 Apr 2021 19:27:53
	(b) (4)	

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered '0'	Ashten Sheriff (b) (4)	20 Apr 2021 19:27:53
	(b) (4)	

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:22

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Ashten Sheriff (b) (4) (b) (4)	20 Apr 2021 19:27:53

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:22

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered empty.	Ashten Sheriff (b) (4)	20 Apr 2021 19:27:53
	(b) (4)	

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:22

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered empty.	Ashten Sheriff (b) (4)	20 Apr 2021 19:27:53
	(b) (4)	

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:22

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Apr 2021 19:27:53

US3832043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:22

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 19:27:53

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:42
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:05:55
User closed query 'Per CDM: Response noted, however there is no CM recorded that matches indication 'HEADACHE' (02 Aug 2020) during this timeframe. Please review or else clarify. Thank You.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:27:32
Query 'Per CDM: Response noted, however there is no CM recorded that matches indication 'HEADACHE' (02 Aug 2020) during this timeframe. Please review or else clarify. Thank You.' answered with 'Per Day 8 safety call completed subject denies use or changes in medications ' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	15 Feb 2021 15:12:49
User opened query 'Per CDM: Response noted, however there is no CM recorded that matches indication 'HEADACHE' (02 Aug 2020) during this timeframe. Please review or else clarify. Thank You.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 15:48:02
User closed query 'Per DM CLR: Diary Dose 1 Day 1, indicates that Medication was taken for HEADACHE on 02AUG2020, however, there is no corresponding Con Med recorded that matches this indication (Headache) in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 15:48:02
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2 (05SEP2020), Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Con Med recorded that matches this indication (Pain at Injection Site) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 16:51:13

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Diary Dose 2 Day 2 (05SEP2020), Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Con Med recorded that matches this indication (Pain at Injection Site) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify. ' answered with 'Subject reported headache medication already entered ' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 20:33:41
Query 'Per DM CLR: Diary Dose 1 Day 1, indicates that Medication was taken for HEADACHE on 02AUG2020, however, there is no corresponding Con Med recorded that matches this indication (Headache) in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'UPDATED ' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 20:31:08
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2 (05SEP2020), Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Con Med recorded that matches this indication (Pain at Injection Site) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 09:25:59
User opened query 'Per DM CLR: Diary Dose 1 Day 1, indicates that Medication was taken for HEADACHE on 02AUG2020, however, there is no corresponding Con Med recorded that matches this indication (Headache) in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 09:25:54
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:32:00
User closed query 'Per ETRTR: Please update ConMeds page for SAE "Suspected Bacterial Infection" treatment, thanks.' (Site from CRA).	(b) (4), (b) (6)	26 Oct 2020 19:18:07

PRODUCTION RELEASE (v12.003
EAB) (1725)

1779 of 2006

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:00:22

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Query 'Per ETRTR: Please update ConMeds page for SAE "Suspected Bacterial Infection" treatment, thanks.' answered with 'medications updated. Thank you' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 22:07:22
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 22:00:03
User opened query 'Per ETRTR: Please update ConMeds page for SAE "Suspected Bacterial Infection" treatment, thanks.' (Site from CRA).	(b) (4), (b) (6)	15 Sep 2020 20:08:37
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 15:24:37

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:22

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:40:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:39:00
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 05:16:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 05:16:47
Data point term sent to Coder	System	30 Sep 2020 22:01:55
User entered 'Vancomycin'	(b) (4), (b) (6)	30 Sep 2020 22:01:35

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:22

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:40:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:39:00
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 22:01:35

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:22

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:40:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:39:00
User entered 'Suspected Toxic Shock Syndrome'	(b) (4), (b) (6)	30 Sep 2020 22:01:35

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:22

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:40:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:39:00
User entered '50'	(b) (4), (b) (6)	30 Sep 2020 22:01:35

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:22

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:40:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:39:00
User entered 'Other (OTHER)'	(b) (4), (b) (6)	30 Sep 2020 22:01:35

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:22

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:40:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:39:00
User entered 'mg/mL'	(b) (4), (b) (6)	30 Sep 2020 22:01:35

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:22

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:40:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:39:00
User entered 'three times daily (TID)'	(b) (4), (b) (6)	30 Sep 2020 22:01:35

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:22

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:40:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:39:00
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 22:01:35

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:22

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:40:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:39:00
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	30 Sep 2020 22:01:35

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:22

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:40:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:39:00
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 22:01:35

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:40:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:39:00
User entered '23 Aug 2020'	(b) (4), (b) (6)	30 Sep 2020 22:01:35

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:40:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:39:00
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 22:01:35

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:40:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:39:00
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 22:01:35

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:40:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:39:00
User entered '25 Aug 2020'	(b) (4), (b) (6)	30 Sep 2020 22:01:35

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:40:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:39:00
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 22:01:35

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:40:59
User entered '3'	System	30 Sep 2020 22:01:35

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:40:59
User entered '1'	System	30 Sep 2020 22:01:35

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:40:59
User entered '804 (804)'	System	30 Sep 2020 22:01:35

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:22

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:12:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:39:45
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 22:03:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 22:03:45
Data point term sent to Coder	System	30 Sep 2020 22:02:57
User entered 'Augmentin'	(b) (4), (b) (6)	30 Sep 2020 22:02:41

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:22

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:12:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:39:45
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 22:02:41

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:22

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:12:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:39:45
User entered 'Urinary Tract Infection'	(b) (4), (b) (6)	30 Sep 2020 22:02:41

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:22

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:12:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:39:45
User entered '875/125'	(b) (4), (b) (6)	30 Sep 2020 22:02:41

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:22

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:12:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:39:45
User entered 'mg (mg)'	(b) (4), (b) (6)	30 Sep 2020 22:02:41

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:22

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:12:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:39:45
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 22:02:41

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:22

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:12:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:39:45
User entered 'twice daily (BID)'	(b) (4), (b) (6)	30 Sep 2020 22:02:41

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:22

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:12:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:39:45
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 22:02:41

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:22

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:12:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:39:45
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	30 Sep 2020 22:02:41

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:22

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:12:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:39:45
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 22:02:41

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:12:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:39:45
User entered '25 Aug 2020'	(b) (4), (b) (6)	30 Sep 2020 22:02:41

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:12:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:39:45
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 22:02:41

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:12:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:39:45
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 22:02:41

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:12:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:39:45
User entered '30 Aug 2020'	(b) (4), (b) (6)	30 Sep 2020 22:02:41

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:12:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:39:45
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 22:02:41

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:12:54
User entered '2'	System	30 Sep 2020 22:02:41

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:12:54
User entered '1'	System	30 Sep 2020 22:02:41

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:12:54
User entered '804 (804)'	System	30 Sep 2020 22:02:41

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:22

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:59:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 10:11:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	11 Feb 2021 10:11:07
Data point term sent to Coder	System	09 Feb 2021 20:31:03
Coding entries removed.	Danyel Johnson (b) (4)	09 Feb 2021 20:30:57
DataPoint Verified.	(b) (4)	27 Oct 2020 16:39:59
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 04:13:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	01 Oct 2020 04:13:42
Data point term sent to Coder	System	30 Sep 2020 22:03:58
User entered 'Advil'	(b) (4), (b) (6)	30 Sep 2020 22:03:44

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:22

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:59:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:39:59
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 22:03:44

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:22

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:59:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Un-verified.	(b) (4)	
	Danyel Johnson (b) (4)	09 Feb 2021 20:30:57
	(b) (4)	
User entered 'AR - HEADACHE, FEVER' reason for change: Data Entry Error	Danyel Johnson (b) (4)	09 Feb 2021 20:30:57
	(b) (4)	
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE, FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE, FEVER did not meet the AE reporting criteria.	(b) (4), (b) (6)	20 Nov 2020 17:30:22
' (Site from DM).		
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE, FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE, FEVER did not meet the AE reporting criteria.	Danyel Johnson (b) (4)	13 Nov 2020 13:54:58
	(b) (4)	
' answered with '		
Solicited adverse reaction of HEADACHE, FEVER did not meet the AE reporting criteria.		
' (Site from DM).		

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:22

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE, FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE, FEVER did not meet the AE reporting criteria. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 09:28:17
	(b) (4), (b) (6)	27 Oct 2020 16:39:59
User entered 'Headache, Fever'	(b) (4), (b) (6)	30 Sep 2020 22:03:44

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:22

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:59:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:39:59
User entered '400'	(b) (4), (b) (6)	30 Sep 2020 22:03:44

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:22

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:59:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:39:59
User entered 'mg (mg)'	(b) (4), (b) (6)	30 Sep 2020 22:03:44

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:22

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:59:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:39:59
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 22:03:44

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:22

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:59:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:39:59
User entered 'as needed (PRN)'	(b) (4), (b) (6)	30 Sep 2020 22:03:44

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:59:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:39:59
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 22:03:44

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:22

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:59:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:39:59
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	30 Sep 2020 22:03:44

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:22

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:59:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:39:59
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 22:03:44

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:59:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:39:59
User entered '5 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 22:03:44

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:59:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:39:59
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 22:03:44

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:59:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:39:59
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 22:03:44

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:59:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:39:59
User entered '5 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 22:03:44

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:59:59
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:39:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 22:03:44

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:59:59
User entered empty.	System	30 Sep 2020 22:03:44

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:59:59
User entered empty.	System	30 Sep 2020 22:03:44

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:59:59
User entered empty.	System	30 Sep 2020 22:03:44

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:22

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:17:19
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:20:03
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: ZOSYN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Nov 2020 05:48:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	15 Nov 2020 05:48:38
Data point term sent to Coder	System	13 Nov 2020 13:58:14
DataPoint Un-verified.	Danyel Johnson (b) (4)	13 Nov 2020 13:58:10
Coding entries removed.	(b) (4)	
	Danyel Johnson (b) (4)	13 Nov 2020 13:58:10
User entered 'ZOSYN 3.375 (12.0 g piperacillin/1.5 g tazobactam).' reason for change: Data Entry Error	(b) (4)	
	Danyel Johnson (b) (4)	13 Nov 2020 13:58:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: ZOSYN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Sep 2020 22:05:41
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Sep 2020 22:05:41
	(b) (4)	
Data point term sent to Coder	System	30 Sep 2020 22:05:00

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:22

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Zosyn'	(b) (4), (b) (6)	30 Sep 2020 22:04:52

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:22

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:17:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 22:04:52

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:22

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:17:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered 'Suspected Toxic Shock Syndrome'	(b) (4), (b) (6)	30 Sep 2020 22:04:52

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:22

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:17:19
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:20:42
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
User closed query 'Per CDM re-query: Site response is noted as updated to 13.5 however, this is just adding the two together. Site indicates 12.0 G PIPERACILLIN/1.5 G TAZOBACTAM in the Name of Medication. Please indicate in the Dose per administration 12.0/1.5. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 11:41:25
Query 'Per CDM re-query: Site response is noted as updated to 13.5 however, this is just adding the two together. Site indicates 12.0 G PIPERACILLIN/1.5 G TAZOBACTAM in the Name of Medication. Please indicate in the Dose per administration 12.0/1.5. Thank you.' answered with 'Verified and updated' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	24 Nov 2020 18:35:26
User entered '12.0/1.5' reason for change: Per Query Resolution	Alyssa-Kay Peay (b) (4) (b) (4)	24 Nov 2020 18:35:16
User opened query 'Per CDM re-query: Site response is noted as updated to 13.5 however, this is just adding the two together. Site indicates 12.0 G PIPERACILLIN/1.5 G TAZOBACTAM in the Name of Medication. Please indicate in the Dose per administration 12.0/1.5. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 17:22:13
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 17:22:13
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' ' answered with 'Verified and updated' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	13 Nov 2020 13:58:20
DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	13 Nov 2020 13:58:10

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:22

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '13.5' reason for change: Data Entry Error	Danyel Johnson (b) (4)	13 Nov 2020 13:58:10
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 09:28:36
	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered '3.375'	(b) (4), (b) (6)	30 Sep 2020 22:04:52

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:22

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:17:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered 'g (g)'	(b) (4), (b) (6)	30 Sep 2020 22:04:52

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:22

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:17:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 22:04:52

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:22

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:17:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
Query 'Per CRIO, frequency not specified. Please review and concile' canceled (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 16:47:09
User opened query 'Per CRIO, frequency not specified. Please review and concile' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 16:43:35
User entered 'four times daily (QID)'	(b) (4), (b) (6)	30 Sep 2020 22:04:52

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:17:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 22:04:52

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:22

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:17:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	30 Sep 2020 22:04:52

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:22

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:17:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 22:04:52

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:17:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered '23 Aug 2020'	(b) (4), (b) (6)	30 Sep 2020 22:04:52

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:17:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 22:04:52

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:17:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 22:04:52

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:17:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered '25 Aug 2020'	(b) (4), (b) (6)	30 Sep 2020 22:04:52

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:17:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 22:04:52

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:17:19
User entered '4'	System	30 Sep 2020 22:04:52

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:17:19
User entered '1'	System	30 Sep 2020 22:04:52

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:17:19
User entered '804 (804)'	System	30 Sep 2020 22:04:52

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:22

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:14:31
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:47:14
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 06:34:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 06:34:43
Data point term sent to Coder	System	30 Sep 2020 22:06:01
User entered 'Clindamycin'	(b) (4), (b) (6)	30 Sep 2020 22:05:49

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:22

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:14:31
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 22:05:49

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:22

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:14:31
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered 'Suspected Toxic Shock Syndrome'	(b) (4), (b) (6)	30 Sep 2020 22:05:49

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:22

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:14:31
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered '900'	(b) (4), (b) (6)	30 Sep 2020 22:05:49

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:22

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:14:31
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered 'mg (mg)'	(b) (4), (b) (6)	30 Sep 2020 22:05:49

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:22

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:14:31
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 22:05:49

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:22

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:14:31
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered 'four times daily (QID)'	(b) (4), (b) (6)	30 Sep 2020 22:05:49

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:14:31
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 22:05:49

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:22

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:14:31
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	30 Sep 2020 22:05:49

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:22

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:14:31
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 22:05:49

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:14:31
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered '23 Aug 2020'	(b) (4), (b) (6)	30 Sep 2020 22:05:49

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:14:31
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 22:05:49

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:14:31
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 22:05:49

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:14:31
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered '25 Aug 2020'	(b) (4), (b) (6)	30 Sep 2020 22:05:49

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:14:31
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 22:05:49

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:14:31
User entered '4'	System	30 Sep 2020 22:05:49

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:14:31
User entered '1'	System	30 Sep 2020 22:05:49

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:14:31
User entered '804 (804)'	System	30 Sep 2020 22:05:49

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:22

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:16:08
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:47:14
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 05:50:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 05:50:51
Data point term sent to Coder	System	30 Sep 2020 22:07:05
User entered 'Pepcid'	(b) (4), (b) (6)	30 Sep 2020 22:06:54

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:22

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:16:08
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 22:06:54

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:22

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:16:08
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered 'Gastrointestinal Prophylaxis'	(b) (4), (b) (6)	30 Sep 2020 22:06:54

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:22

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:16:08
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered '20'	(b) (4), (b) (6)	30 Sep 2020 22:06:54

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:22

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:16:08
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered 'mg (mg)'	(b) (4), (b) (6)	30 Sep 2020 22:06:54

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:22

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:16:08
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 22:06:54

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:22

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:16:08
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered 'twice daily (BID)'	(b) (4), (b) (6)	30 Sep 2020 22:06:54

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:22

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:16:08
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 22:06:54

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:22

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:16:08
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	30 Sep 2020 22:06:54

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:22

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:16:08
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 22:06:54

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:16:08
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered '23 Aug 2020'	(b) (4), (b) (6)	30 Sep 2020 22:06:54

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:16:08
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 22:06:54

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:16:08
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 22:06:54

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:16:08
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered '25 Aug 2020'	(b) (4), (b) (6)	30 Sep 2020 22:06:54

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:16:08
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:14
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 22:06:54

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:16:08
User entered '2'	System	30 Sep 2020 22:06:54

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:16:08
User entered '1'	System	30 Sep 2020 22:06:54

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:16:08
User entered '804 (804)'	System	30 Sep 2020 22:06:54

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:22

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Apr 2021 19:25:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 19:25:45
Data point term sent to Coder	System	20 Apr 2021 19:24:05
User entered 'Zyrtec'	Ashten Sheriff (b) (4)	20 Apr 2021 19:23:18
	(b) (4)	

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered 'No (N)'	Ashten Sheriff (b) (4)	20 Apr 2021 19:23:18
	(b) (4)	

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
User entered 'Seasonal Allergies'	(b) (4) Ashten Sheriff (b) (4) (b) (4)	20 Apr 2021 19:23:18

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:22

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered '10'	Ashten Sheriff (b) (4)	20 Apr 2021 19:23:18
	(b) (4)	

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:22

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered 'mg (mg)'	Ashten Sheriff (b) (4)	20 Apr 2021 19:23:18
	(b) (4)	

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered empty.	Ashten Sheriff (b) (4)	20 Apr 2021 19:23:18
	(b) (4)	

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:22

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered 'as needed (PRN)'	Ashten Sheriff (b) (4)	20 Apr 2021 19:23:18
	(b) (4)	

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:22

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered empty.	Ashten Sheriff (b) (4)	20 Apr 2021 19:23:18
	(b) (4)	

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:22

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
User entered 'Oral (ORAL)'	(b) (4) Ashten Sheriff (b) (4)	20 Apr 2021 19:23:18
	(b) (4)	

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered empty.	Ashten Sheriff (b) (4)	20 Apr 2021 19:23:18
	(b) (4)	

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered 'un UNK 2015'	Ashten Sheriff (b) (4)	20 Apr 2021 19:23:18
	(b) (4)	

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered '0'	Ashten Sheriff (b) (4)	20 Apr 2021 19:23:18
	(b) (4)	

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:22

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	20 Apr 2021 19:23:18
	(b) (4)	

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered empty.	Ashten Sheriff (b) (4)	20 Apr 2021 19:23:18
	(b) (4)	

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered 'No (N)'	Ashten Sheriff (b) (4)	20 Apr 2021 19:23:18
	(b) (4)	

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 19:23:18

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 19:23:18

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 19:23:18

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:22

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Apr 2021 19:40:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 19:40:41
Data point term sent to Coder	System	20 Apr 2021 19:25:06
User entered 'Albuterol'	Ashten Sheriff (b) (4) (b) (4)	20 Apr 2021 19:24:58

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered 'No (N)'	Ashten Sheriff (b) (4)	20 Apr 2021 19:24:58
	(b) (4)	

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
User entered 'Adverse Event Worsening of Seasonal Allergies'	(b) (4) Ashten Sheriff (b) (4) (b) (4)	20 Apr 2021 19:24:58

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:22

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered '90'	Ashten Sheriff (b) (4)	20 Apr 2021 19:24:58
	(b) (4)	

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:22

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered 'ug (ug)'	Ashten Sheriff (b) (4)	20 Apr 2021 19:24:58
	(b) (4)	

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:22

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered empty.	Ashten Sheriff (b) (4)	20 Apr 2021 19:24:58
	(b) (4)	

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:22

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered 'as needed (PRN)'	Ashten Sheriff (b) (4)	20 Apr 2021 19:24:58
	(b) (4)	

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered empty.	Ashten Sheriff (b) (4)	20 Apr 2021 19:24:58
	(b) (4)	

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:22

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Ashten Sheriff (b) (4) (b) (4)	20 Apr 2021 19:24:58

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered empty.	Ashten Sheriff (b) (4)	20 Apr 2021 19:24:58
	(b) (4)	

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:22

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

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered '14 Apr 2021'	Ashten Sheriff (b) (4)	20 Apr 2021 19:24:58
	(b) (4)	

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered '0'	Ashten Sheriff (b) (4)	20 Apr 2021 19:24:58
	(b) (4)	

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:22

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	20 Apr 2021 19:24:58
	(b) (4)	

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered empty.	Ashten Sheriff (b) (4)	20 Apr 2021 19:24:58
	(b) (4)	

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:18:45
	(b) (4)	
User entered 'No (N)'	Ashten Sheriff (b) (4)	20 Apr 2021 19:24:58
	(b) (4)	

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 19:24:58

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 19:24:58

US3832043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 19:24:58

US3832043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:00:22

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:42
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:50:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 22:34:39

US3832043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:00:22

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:50:41
User entered '23 Aug 2020'	(b) (4), (b) (6)	30 Sep 2020 22:35:14

US3832043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:00:22

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:50:41
User entered 'Chest X-Ray'	(b) (4), (b) (6)	30 Sep 2020 22:35:14

US3832043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:00:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:50:41
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	30 Sep 2020 22:35:14

US3832043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:00:22

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:50:41
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 22:35:14

US3832043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:00:22

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:50:41
User entered '24 Aug 2020'	(b) (4), (b) (6)	30 Sep 2020 22:36:24

US3832043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:00:22

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:50:41
User entered 'Abdominal CT Scan'	(b) (4), (b) (6)	30 Sep 2020 22:36:24

US3832043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:00:22

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:50:41
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	30 Sep 2020 22:36:24

US3832043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:00:22

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:50:41
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 22:36:24

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 19:54:50
User entered	System	07 Sep 2020 19:53:34
'USA-US100-2020-MRNA-1273-P301000001'		

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 19:54:50
User entered 'Yes (Y)'	System	07 Sep 2020 19:53:34

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 19:54:50
User entered 'No (N)'	System	07 Sep 2020 19:53:34

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 19:54:50
User entered 'No (N)'	System	07 Sep 2020 19:53:34

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 19:54:50
User entered 'Yes (Y)'	System	07 Sep 2020 19:53:34

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 19:54:50
User entered 'No (N)'	System	07 Sep 2020 19:53:34

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 19:54:50
User entered 'No (N)'	System	07 Sep 2020 19:53:34

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 19:54:50
User entered 'No (N)'	System	07 Sep 2020 19:53:34

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:59:42
Amendment Manager: User entered 'Gowdhami'	System	14 Sep 2020 21:42:16

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:59:42
Amendment Manager: User entered 'Mohan'	System	14 Sep 2020 21:42:16

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:59:42
Amendment Manager: User entered '1655 E. Greenville St'	System	14 Sep 2020 21:42:16

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:59:42
Amendment Manager: User entered 'Anderson'	System	14 Sep 2020 21:42:16

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:59:42
Amendment Manager: User entered 'SC'	System	14 Sep 2020 21:42:16

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:59:42
Amendment Manager: User entered '29621'	System	14 Sep 2020 21:42:16

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:59:42
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:19:55
User entered 'US' (non-conformant).	System	07 Sep 2020 19:54:57

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
	(b) (4)	
User entered '3'	System	14 Oct 2020 16:02:47
User entered '2'	System	01 Oct 2020 16:59:55
User entered '1'	System	07 Sep 2020 19:54:57

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 19:54:50
User entered		
'USA-US100-2020-MRNA-1273-P301000001'	System	07 Sep 2020 19:53:34

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 19:54:50
User entered 'Yes (Y)'	System	07 Sep 2020 19:53:34

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 19:54:50
User entered 'No (N)'	System	07 Sep 2020 19:53:34

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 19:54:50
User entered 'No (N)'	System	07 Sep 2020 19:53:34

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 19:54:50
User entered 'Yes (Y)'	System	07 Sep 2020 19:53:34

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 19:54:50
User entered 'No (N)'	System	07 Sep 2020 19:53:34

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 19:54:50
User entered 'No (N)'	System	07 Sep 2020 19:53:34

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 19:54:50
User entered 'No (N)'	System	07 Sep 2020 19:53:34

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:59:42
Amendment Manager: User entered 'Gowdhami'	System	14 Sep 2020 21:42:16

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:59:42
Amendment Manager: User entered 'Mohan'	System	14 Sep 2020 21:42:16

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:59:42
Amendment Manager: User entered '1655 E. Greenville St'	System	14 Sep 2020 21:42:16

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:59:42
Amendment Manager: User entered 'Anderson'	System	14 Sep 2020 21:42:16

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:59:42
Amendment Manager: User entered 'SC'	System	14 Sep 2020 21:42:16

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:59:42
Amendment Manager: User entered '29621'	System	14 Sep 2020 21:42:16

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:59:42
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:19:55
User entered 'US' (non-conformant).	System	07 Sep 2020 19:54:57

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
	(b) (4)	
User entered '3'	System	14 Oct 2020 16:02:47
User entered '2'	System	01 Oct 2020 16:59:55
User entered '1'	System	07 Sep 2020 19:54:57

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:00:22

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:27:58
User entered '07/Sep/2020 15:54'	System	07 Sep 2020 19:54:57

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:00:22

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:27:58
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:59:42
User entered 'I'	(b) (4), (b) (6)	07 Sep 2020 19:54:57

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 19:54:50
User entered	System	07 Sep 2020 19:53:34
'USA-US100-2020-MRNA-1273-P301000001'		

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 19:54:50
User entered 'Yes (Y)'	System	07 Sep 2020 19:53:34

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 19:54:50
User entered 'No (N)'	System	07 Sep 2020 19:53:34

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 19:54:50
User entered 'No (N)'	System	07 Sep 2020 19:53:34

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 19:54:50
User entered 'Yes (Y)'	System	07 Sep 2020 19:53:34

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 19:54:50
User entered 'No (N)'	System	07 Sep 2020 19:53:34

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 19:54:50
User entered 'No (N)'	System	07 Sep 2020 19:53:34

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 19:54:50
User entered 'No (N)'	System	07 Sep 2020 19:53:34

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:59:42
Amendment Manager: User entered 'Gowdhami'	System	14 Sep 2020 21:42:16

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:59:42
Amendment Manager: User entered 'Mohan'	System	14 Sep 2020 21:42:16

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:59:42
Amendment Manager: User entered '1655 E. Greenville St'	System	14 Sep 2020 21:42:16

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:59:42
Amendment Manager: User entered 'Anderson'	System	14 Sep 2020 21:42:16

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:59:42
Amendment Manager: User entered 'SC'	System	14 Sep 2020 21:42:16

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:59:42
Amendment Manager: User entered '29621'	System	14 Sep 2020 21:42:16

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:59:42
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:19:55
User entered 'US' (non-conformant).	System	07 Sep 2020 19:54:57

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
	(b) (4)	
User entered '3'	System	14 Oct 2020 16:02:47
User entered '2'	System	01 Oct 2020 16:59:55
User entered '1'	System	07 Sep 2020 19:54:57

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:00:22

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:28:00
User entered '01/Oct/2020 16:59'	System	01 Oct 2020 16:59:55

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:00:22

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:28:00
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 16:02:37
User entered 'I'	(b) (4), (b) (6)	01 Oct 2020 16:59:55

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 19:54:50
User entered		
'USA-US100-2020-MRNA-1273-P301000001'	System	07 Sep 2020 19:53:34

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 19:54:50
User entered 'Yes (Y)'	System	07 Sep 2020 19:53:34

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 19:54:50
User entered 'No (N)'	System	07 Sep 2020 19:53:34

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 19:54:50
User entered 'No (N)'	System	07 Sep 2020 19:53:34

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 19:54:50
User entered 'Yes (Y)'	System	07 Sep 2020 19:53:34

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 19:54:50
User entered 'No (N)'	System	07 Sep 2020 19:53:34

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 19:54:50
User entered 'No (N)'	System	07 Sep 2020 19:53:34

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 19:54:50
User entered 'No (N)'	System	07 Sep 2020 19:53:34

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:59:42
Amendment Manager: User entered 'Gowdhami'	System	14 Sep 2020 21:42:16

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:59:42
Amendment Manager: User entered 'Mohan'	System	14 Sep 2020 21:42:16

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:59:42
Amendment Manager: User entered '1655 E. Greenville St'	System	14 Sep 2020 21:42:16

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:59:42
Amendment Manager: User entered 'Anderson'	System	14 Sep 2020 21:42:16

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:59:42
Amendment Manager: User entered 'SC'	System	14 Sep 2020 21:42:16

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:59:42
Amendment Manager: User entered '29621'	System	14 Sep 2020 21:42:16

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:28:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:59:42
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:19:55
User entered 'US' (non-conformant).	System	07 Sep 2020 19:54:57

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
	(b) (4)	
User entered '3'	System	14 Oct 2020 16:02:47
User entered '2'	System	01 Oct 2020 16:59:55
User entered '1'	System	07 Sep 2020 19:54:57

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:00:22

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:28:03
User entered '14/Oct/2020 16:02'	System	14 Oct 2020 16:02:47

US3832043

Folder: SAE USA-US100-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:00:22

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:58:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:28:03
User entered 'I'	(b) (4), (b) (6)	14 Oct 2020 16:02:47