

US3822181 (Prod: Tryon Medical Partners, PLLC)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:56:07

All time stamps listed in this document are displayed in GMT

US3822181

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 21:10:47

Generated On: 10 Jun 2021 09:56:07

[Participant ID](#)

US3822181

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

US3822181

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 20:04:02

Generated On: 10 Jun 2021 09:56:07

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	19 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 14 Feb 2021 20:04:02

Generated On: 10 Jun 2021 09:56:07

Date of Birth (MMM yyyy)	(b) (6) 1995
Age	25
Age Units	YEARS
Age (Derived)	25
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 14 Feb 2021 20:04:02

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Date of Informed Consent (<i>dd MMM yyyy</i>)	19 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☒
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 14 Feb 2021 20:04:02

Generated On: 10 Jun 2021 09:56:07

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 14 Feb 2021 20:04:02

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 14 Feb 2021 20:04:02

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Condition	ECZEMA
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 14 Feb 2021 20:04:02

Generated On: 10 Jun 2021 09:56:07

Condition	HEMORRHOIDS
Start date (dd MMM yyyy)	UN UNK 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 14 Feb 2021 20:04:02

Generated On: 10 Jun 2021 09:56:07

Condition	ERECTILE DYSFUNCTION
Start date (dd MMM yyyy)	UN UNK 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 14 Feb 2021 20:04:02

Generated On: 10 Jun 2021 09:56:07

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	19 AUG 2020
Time of assessment (00:00-23:59)	07:45 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 07:45
Height (xxx.x)	73.1 in
Weight (xxx.x)	231.2 lb
BMI (xxx.x)	30.48337 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 20:04:02

Generated On: 10 Jun 2021 09:56:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 14 Feb 2021 20:04:02

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 14 Feb 2021 20:04:02

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 20:04:02

Generated On: 10 Jun 2021 09:56:07

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	19 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 14 Feb 2021 20:04:02

Generated On: 10 Jun 2021 09:56:07

What was the date of randomization? (dd MMM yyyy) 19 AUG 2020

What was the participant's randomization number? 105714

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 14 Feb 2021 20:04:02

Generated On: 10 Jun 2021 09:56:07

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 14 Feb 2021 20:04:02

Generated On: 10 Jun 2021 09:56:07

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	19 AUG 2020
Time of assessment (00:00-23:59)	07:45 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 07:45
Temperature (xxx.x)	97.9 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 14 Feb 2021 20:04:02

Generated On: 10 Jun 2021 09:56:07

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	19 AUG 2020
Time of assessment (00:00-23:59)	08:57 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 08:57
Temperature (xxx.x)	98.4 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 20:04:02

Generated On: 10 Jun 2021 09:56:07

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 14 Feb 2021 20:04:02

Generated On: 10 Jun 2021 09:56:07

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) 19 AUG 2020

What was the treatment time? (00:00-23:59) 08:26 (24 HR)

Treatment Date and Time (derived) 19 AUG 2020 08:26

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Feb 2021 20:04:02

Generated On: 10 Jun 2021 09:56:07

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 AUG 2020

Collection time (00:00-23:59)

07:55 (24 HR)

Collection date and time (derived)

19 AUG 2020 07:55

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 14 Feb 2021 20:04:02

Generated On: 10 Jun 2021 09:56:07

Collection date (dd MMM yyyy)			19 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:06	19 AUG 2020 08:06
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 20:04:02

Generated On: 10 Jun 2021 09:56:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

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

98.4 °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

19 AUG 2020 08:47

PC Open Date & Time

19 AUG 2020 08:46

PC Close Date & Time

19 AUG 2020 11:16

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

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	19 AUG 2020 17:34
PC Open Date & Time	19 AUG 2020 12:11
PC Close Date & Time	20 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 21:07

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 16:47

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

22 AUG 2020 22:27

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:56:07

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

98.2 °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

23 AUG 2020 19:52

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:56:07

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 21:34

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 07:40

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 08:48

PC Open Date & Time

19 AUG 2020 08:46

PC Close Date & Time

19 AUG 2020 11:16

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

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

19 AUG 2020 17:35

PC Open Date & Time

19 AUG 2020 12:11

PC Close Date & Time

20 AUG 2020 11:59

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:56:07

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

20 AUG 2020 21:07

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 16:47

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:56:07

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

22 AUG 2020 22:27

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:56:07

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

23 AUG 2020 19:53

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:56:07

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

24 AUG 2020 21:34

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:56:07

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

26 AUG 2020 07:40

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

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 ☐

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 08:48
PC Open Date & Time	19 AUG 2020 08:46
PC Close Date & Time	19 AUG 2020 11:16

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

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 ☐

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 17:35
PC Open Date & Time	19 AUG 2020 12:11
PC Close Date & Time	20 AUG 2020 11:59

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:56:07

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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:56:07

Yes ☐	
PC Time stamp	20 AUG 2020 21:07
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:56:07

Yes ☐	
PC Time stamp	21 AUG 2020 16:48
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:56:07

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

EAB) (1725)

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US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:56:07

Yes ☐	
PC Time stamp	22 AUG 2020 22:28
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:56:07

Yes ☐	
PC Time stamp	23 AUG 2020 19:53
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:56:07

Yes ☐	
PC Time stamp	24 AUG 2020 21:34
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:56:07

Yes ☐	
PC Time stamp	26 AUG 2020 07:40
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3822181

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 20:04:02

Generated On: 10 Jun 2021 09:56:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822181

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 20:04:02

Generated On: 10 Jun 2021 09:56:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822181

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 20:04:02

Generated On: 10 Jun 2021 09:56:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822181

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 20:04:02

Generated On: 10 Jun 2021 09:56:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822181

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 20:04:02

Generated On: 10 Jun 2021 09:56:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822181

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 20:04:02

Generated On: 10 Jun 2021 09:56:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822181

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 20:04:12

Generated On: 10 Jun 2021 09:56:07

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	24 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3822181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 14 Feb 2021 20:04:12

Generated On: 10 Jun 2021 09:56:07

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	24 SEP 2020
Time of assessment (00:00-23:59)	07:19 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 07:19
Temperature (xxx.x)	98.7 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3822181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 14 Feb 2021 20:04:12

Generated On: 10 Jun 2021 09:56:07

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	24 SEP 2020
Time of assessment (00:00-23:59)	08:23 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 08:23
Temperature (xxx.x)	98.7 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3822181

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 20:04:03

Generated On: 10 Jun 2021 09:56:07

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.

US3822181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 14 Feb 2021 20:04:03

Generated On: 10 Jun 2021 09:56:07

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) 24 SEP 2020

What was the treatment time? (00:00-23:59) 07:53 (24 HR)

Treatment Date and Time (derived) 24 SEP 2020 07:53

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

US3822181

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Feb 2021 20:04:03

Generated On: 10 Jun 2021 09:56:07

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 SEP 2020

Collection time (00:00-23:59)

07:29 (24 HR)

Collection date and time (derived)

24 SEP 2020 07:29

US3822181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 14 Feb 2021 20:04:02

Generated On: 10 Jun 2021 09:56:07

Collection date (dd MMM yyyy)			24 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	07:33	24 SEP 2020 07:33
Nasopharyngeal Swab 2	No		

US3822181

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 20:04:03

Generated On: 10 Jun 2021 09:56:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

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

98.7 °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

24 SEP 2020 08:16

PC Open Date & Time

24 SEP 2020 08:13

PC Close Date & Time

24 SEP 2020 10:43

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	24 SEP 2020 21:43
PC Open Date & Time	24 SEP 2020 11:38
PC Close Date & Time	25 SEP 2020 11:59

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:56:07

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	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes ☒
	No ☐

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	25 SEP 2020 18:51
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:56:07

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 09:16

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:56:07

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

96.2 °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

28 SEP 2020 10:12

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:56:07

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

98.4 °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

28 SEP 2020 21:03

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 22:06

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 23:10

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

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

24 SEP 2020 08:16

PC Open Date & Time

24 SEP 2020 08:13

PC Close Date & Time

24 SEP 2020 10:43

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

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

24 SEP 2020 21:43

PC Open Date & Time

24 SEP 2020 11:38

PC Close Date & Time

25 SEP 2020 11:59

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:56:07

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

25 SEP 2020 18:51

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 09:16

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:56:07

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

28 SEP 2020 10:12

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:56:07

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

28 SEP 2020 21:03

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:56:07

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

29 SEP 2020 22:05

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:56:07

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

30 SEP 2020 23:10

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

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 ☐

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 08:16
PC Open Date & Time	24 SEP 2020 08:13
PC Close Date & Time	24 SEP 2020 10:43

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

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 ☐

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 21:43
PC Open Date & Time	24 SEP 2020 11:38
PC Close Date & Time	25 SEP 2020 11:59

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:56:07

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:56:07

Yes ☐	
PC Time stamp	25 SEP 2020 18:52
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:56:07

Yes ☐	
PC Time stamp	27 SEP 2020 09:17
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:56:07

Yes ☐	
PC Time stamp	28 SEP 2020 10:12
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:56:07

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 ☒

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EAB) (1725)

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:56:07

Yes ☐	
PC Time stamp	28 SEP 2020 21:03
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:56:07

Yes ☐	
PC Time stamp	29 SEP 2020 22:05
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:56:07

Yes ☐	
PC Time stamp	30 SEP 2020 23:10
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3822181

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 20:04:02

Generated On: 10 Jun 2021 09:56:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822181

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 20:04:02

Generated On: 10 Jun 2021 09:56:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822181

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 20:04:02

Generated On: 10 Jun 2021 09:56:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822181

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 20:04:02

Generated On: 10 Jun 2021 09:56:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822181

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 20:04:02

Generated On: 10 Jun 2021 09:56:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822181

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 20:04:02

Generated On: 10 Jun 2021 09:56:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822181

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 20:04:13

Generated On: 10 Jun 2021 09:56:07

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	22 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3822181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 14 Feb 2021 20:04:13

Generated On: 10 Jun 2021 09:56:07

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	22 OCT 2020
Time of assessment (00:00-23:59)	07:25 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 07:25
Temperature (xxx.x)	98.1 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3822181

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 20:04:13

Generated On: 10 Jun 2021 09:56:07

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.

US3822181

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Feb 2021 20:04:13

Generated On: 10 Jun 2021 09:56:07

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 OCT 2020

Collection time (00:00-23:59)

07:31 (24 HR)

Collection date and time (derived)

22 OCT 2020 07:31

US3822181

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 20:04:13

Generated On: 10 Jun 2021 09:56:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

22 OCT 2020 18:00:10

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3822181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

28 OCT 2020 20:00:28

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3822181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

04 NOV 2020 14:33:05

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3822181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 12:01:20

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 NOV 2020 11:19:37
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 NOV 2020 12:00:22

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 DEC 2020 12:00:34
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 DEC 2020 22:03:12

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

20 DEC 2020 12:14:16

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 DEC 2020 07:49:18
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

01 JAN 2021 09:50:46

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

09 JAN 2021 08:23:11

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

17 JAN 2021 13:13:43

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 06:00:56

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 JAN 2021 22:29:48

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

07 FEB 2021 12:03:44

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 12:03:59
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 16:21:22

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 12:36:26

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

05 MAR 2021 07:38:37

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

14 MAR 2021 12:30:26

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 12:28:33

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

28 MAR 2021 12:21:56

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

04 APR 2021 12:14:41

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

11 APR 2021 12:00:35

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

18 APR 2021 12:10:09

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

25 APR 2021 12:40:51

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 MAY 2021 12:31:18
Patient Cloud Open Date & Time	30 APR 2021 00:01
Patient Cloud Close Date & Time	04 MAY 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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 ☐

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 327

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

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

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

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

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Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 334

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

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

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

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Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 341

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

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27 JUL 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 348

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

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03 AUG 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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 ☐

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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 ☐

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

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17 AUG 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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 ☐

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 376

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

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

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

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

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

Fever (Temperature $\geq$ 100.4°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 ☐

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 383

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

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

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Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

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Form: Safety Follow Up Diary

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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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 ☐

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Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

US3822181

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Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 397

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

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

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

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Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

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21 SEP 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 404

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 411

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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 ☐

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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 ☐

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 460

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 516

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

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

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

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

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

Fever (Temperature $\geq$ 100.4°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 ☐

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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 ☐

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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 ☐

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

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08 FEB 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

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22 FEB 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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 ☐

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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 ☐

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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 ☐

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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 ☐

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

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22 MAR 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 600

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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 ☐

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 621

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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 ☐

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

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17 MAY 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

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24 MAY 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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 ☐

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

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31 MAY 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

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07 JUN 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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 ☐

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

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05 JUL 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 691

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

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08 JUL 2022 00:01

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12 JUL 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

Date and time of submission

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15 JUL 2022 00:01

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19 JUL 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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 ☐

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

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26 JUL 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

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29 JUL 2022 00:01

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02 AUG 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

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09 AUG 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 726

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

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

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

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

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

Fever (Temperature $\geq$ 100.4°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 ☐

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

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12 AUG 2022 00:01

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16 AUG 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 733

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

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

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

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

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

Fever (Temperature $\geq$ 100.4°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 ☐

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

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23 AUG 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

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26 AUG 2022 00:01

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30 AUG 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

Date and time of submission

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06 SEP 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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 ☐

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

Date and time of submission

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13 SEP 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

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16 SEP 2022 00:01

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20 SEP 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

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

Date and time of submission

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23 SEP 2022 00:01

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27 SEP 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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 ☐

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

Date and time of submission

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04 OCT 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

DAY 796

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3822181

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:56:07

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		05 MAR 2021 07:38:28

US3822181

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:14:22

Generated On: 10 Jun 2021 09:56:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822181

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:14:22

Generated On: 10 Jun 2021 09:56:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822181

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:10:48

Generated On: 10 Jun 2021 09:56:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822181

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:10:48

Generated On: 10 Jun 2021 09:56:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822181

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:10:48

Generated On: 10 Jun 2021 09:56:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822181

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:10:48

Generated On: 10 Jun 2021 09:56:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822181

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:10:48

Generated On: 10 Jun 2021 09:56:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822181

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:10:48

Generated On: 10 Jun 2021 09:56:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822181

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:10:48

Generated On: 10 Jun 2021 09:56:07

Was this visit performed?	Yes ☒
	No ☐

Visit date (dd MMM yyyy)	25 MAR 2021

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

Folder OID	VISIT4

US3822181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 21:10:48

Generated On: 10 Jun 2021 09:56:07

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) _____

US3822181

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:10:48

Generated On: 10 Jun 2021 09:56:07

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.

US3822181

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 21:10:48

Generated On: 10 Jun 2021 09:56:07

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	25 MAR 2021
Collection time (00:00-23:59)	07:15 (24 HR)
Collection date and time (derived)	25 MAR 2021 07:15

US3822181

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:10:48

Generated On: 10 Jun 2021 09:56:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822181

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

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

US3822181

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:07

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3822181

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:56:07

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

US3822181

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:56:07

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3822181

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:10:48

Generated On: 10 Jun 2021 09:56:07

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	07 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	UNBLND_DECIDE

US3822181

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

Form: Unblinding

Data signed: (b) (4) 23 Apr 2021 14:40:00

Generated On: 10 Jun 2021 09:56:07

Date of updated informed consent (dd MMM yyyy) 07 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) 06 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 _____

US3822181

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 21:10:48

Generated On: 10 Jun 2021 09:56:07

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	07 JAN 2021
Collection time (00:00-23:59)	16:26 (24 HR)
Collection date and time (derived)	07 JAN 2021 16:26

US3822181

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 21:10:48

Generated On: 10 Jun 2021 09:56:07

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	07 JAN 2021
Collection time (00:00 - 23:59)	16:48
Collection Date and Time (derived)	07 JAN 2021 16:48

US3822181

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 20:11:00

Generated On: 10 Jun 2021 09:56:07

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Mar 2021 17:47:30

Generated On: 10 Jun 2021 09:56:07

AEID	USA-US126-2021-MRNA-1273-P30 1000006
Adverse event	APPENDICITIS
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)	3 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	4 MAR 2021
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	True
Hospital Admission Date (dd MMM yyyy)	3 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	4 MAR 2021
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐

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EAB) (1725)

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US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Mar 2021 17:47:30

Generated On: 10 Jun 2021 09:56:07

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 ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Mar 2021 17:47:30

Generated On: 10 Jun 2021 09:56:07

RN SPOKE WITH PATIENT VIA
PHONE CALL ON 04MAR2021
DUE TO PATIENT MISSING HIS 7
AM PATIENT. PATIENT STATES
THAT HE BEGAN TO HAVE
STOMACH PAINS ON
03MAR2021 SO HE WENT TO
THE HOSPITAL. PATIENT WAS
DIAGNOSED WITH
APPENDICITIS AND HAD TO
HAVE AN APPENDECTOMY ON
04MAR2021 EVENING.

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

US3822181

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Mar 2021 17:47:30

Generated On: 10 Jun 2021 09:56:07

AEID	
Adverse event	C DIFF
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)	9 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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EAB) (1725)

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US3822181

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Mar 2021 17:47:30

Generated On: 10 Jun 2021 09:56:07

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

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 21:10:48

Generated On: 10 Jun 2021 09:56:07

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

Yes ☒

No ☐

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

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 21:10:47

Generated On: 10 Jun 2021 09:56:07

Name of Medication PREPARATION H CREAM

Prophylaxis Yes ☐
No ☒

Indication HEMORRHOIDS

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 21:10:47

Generated On: 10 Jun 2021 09:56:07

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

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 21:10:47

Generated On: 10 Jun 2021 09:56:07

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA

Dose per administration .5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 21:10:47

Generated On: 10 Jun 2021 09:56:07

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

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 21:10:47

Generated On: 10 Jun 2021 09:56:07

Name of Medication ALEVE

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE PAIN

Dose per administration 220

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 21:10:47

Generated On: 10 Jun 2021 09:56:07

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 25 SEP 2020		
Was this medication taken for solicited event?	Yes	☒
	No	☐
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 21:10:47

Generated On: 10 Jun 2021 09:56:07

Name of Medication MUCINEX

Prophylaxis Yes ☐
No ☒

Indication COUGH

Dose per administration 600

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)

330 of 1797

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 21:10:47

Generated On: 10 Jun 2021 09:56:07

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☒
	No	☐
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 21:10:47

Generated On: 10 Jun 2021 09:56:07

Name of Medication VANCOMYCIN HCL

Prophylaxis Yes ☐
No ☒

Indication C DIFF

Dose per administration 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
EAB) (1725)

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US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 21:10:47

Generated On: 10 Jun 2021 09:56:07

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 Apr 2021 21:10:47

Generated On: 10 Jun 2021 09:56:07

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication POST APPENDECTOMY

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)

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US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 Apr 2021 21:10:47

Generated On: 10 Jun 2021 09:56:07

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	3 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 9 MAR 2021		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3822181

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 21:10:48

Generated On: 10 Jun 2021 09:56:07

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3822181

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 02 Apr 2021 21:10:48

Generated On: 10 Jun 2021 09:56:07

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
3 MAR 2021	APPENDECTOMY	Adverse Event	
3 MAR 2021	CT SCAN OF ABDOMEN FOR APPENDICITIS	Adverse Event	

US3822181

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:56:07

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

US3822181

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:56:07

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 ☐

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 12 Apr 2021 00:04:51

Generated On: 10 Jun 2021 09:56:07

SAEID	USA-US126-2021-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NORTH CAROLINA
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Apr 2021 00:04:51

Generated On: 10 Jun 2021 09:56:07

SAEID	USA-US126-2021-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NORTH CAROLINA
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	05/MAR/2021 10:28
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

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 12 Apr 2021 00:04:51

Generated On: 10 Jun 2021 09:56:07

SAEID	USA-US126-2021-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NORTH CAROLINA
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	24/MAR/2021 13:41
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

US3822181 (Prod: Tryon Medical Partners, PLLC)

US3822181

Form: Participant Creation

Generated On: 10 Jun 2021 09:56:07

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'US3822181'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 11:54:29

US3822181

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:56:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	15 Sep 2020 23:50:26

US3822181

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '19 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 11:54:30

US3822181

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:56:07

[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 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Clinic (Clinic)'	Kelly Woodell (b) (4)	15 Sep 2020 23:50:26

US3822181

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:56:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User entered 'SCRN'	System	15 Sep 2020 23:50:26

US3822181

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:56:07

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered (b) (6) 1995'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 11:54:31

US3822181

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:56:07

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '25'	Kelly Woodell (b) (4)	02 Sep 2020 16:16:52

US3822181

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:56:07

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User entered 'YEARS'	System	02 Sep 2020 16:16:52

US3822181

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:56:07

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User entered '25'	System	19 Aug 2020 12:39:18

US3822181

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:56:07

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Male (M)'	Kelly Woodell (b) (4)	02 Sep 2020 16:16:52

US3822181

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:56:07

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Kelly Woodell (b) (4)	02 Sep 2020 16:16:52

US3822181

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:56:07

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '1'	Kelly Woodell (b) (4)	02 Sep 2020 16:16:52

US3822181

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:56:07

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '0'	Kelly Woodell (b) (4)	02 Sep 2020 16:16:52

US3822181

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:56:07

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '0'	Kelly Woodell (b) (4)	02 Sep 2020 16:16:52

US3822181

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:56:07

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '0'	Kelly Woodell (b) (4)	02 Sep 2020 16:16:52

US3822181

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:56:07

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '0'	Kelly Woodell (b) (4)	02 Sep 2020 16:16:52

US3822181

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:56:07

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '0'	Kelly Woodell (b) (4)	02 Sep 2020 16:16:52

US3822181

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:56:07

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered empty.	Kelly Woodell (b) (4)	02 Sep 2020 16:16:52

US3822181

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:56:07

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '0'	Kelly Woodell (b) (4)	02 Sep 2020 16:16:52

US3822181

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:56:07

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '0'	Kelly Woodell (b) (4)	02 Sep 2020 16:16:52

US3822181

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '19 Aug 2020'	Kelly Woodell (b) (4)	19 Aug 2020 12:39:18

US3822181

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User entered 'Aug 2020'	System	19 Aug 2020 12:39:18

US3822181

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User entered '2020'	System	19 Aug 2020 12:39:18

US3822181

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:56:07

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Amendment 2 (2)'	Kelly Woodell (b) (4)	19 Aug 2020 12:39:18

US3822181

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	19 Aug 2020 12:39:18

US3822181

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:56:07

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered empty.	Kelly Woodell (b) (4)	19 Aug 2020 12:39:18

US3822181

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:56:07

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered empty.	Kelly Woodell (b) (4)	19 Aug 2020 12:39:18

US3822181

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:56:07

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'No (N)'	Kelly Woodell (b) (4)	19 Aug 2020 12:39:18

US3822181

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:56:07

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 11:54:30

US3822181

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:56:07

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User entered '1'	System	19 Aug 2020 12:39:25

US3822181

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	19 Aug 2020 12:39:25

US3822181

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:56:07

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	15 Sep 2020 23:50:53

US3822181

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:56:07

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Eczema, LLT: Eczema - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 23:52:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 23:52:46
Data point term sent to Coder	System	15 Sep 2020 23:51:25
User entered 'eczema'	Kelly Woodell (b) (4)	15 Sep 2020 23:51:14

US3822181

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'un UNK 2018'	Kelly Woodell (b) (4)	15 Sep 2020 23:51:14

US3822181

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:56:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '0'	Kelly Woodell (b) (4)	15 Sep 2020 23:51:14

US3822181

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:56:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	15 Sep 2020 23:51:14

US3822181

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered empty.	Kelly Woodell (b) (4)	15 Sep 2020 23:51:14

US3822181

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:56:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '0'	Kelly Woodell (b) (4)	15 Sep 2020 23:51:14

US3822181

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User entered 'Jan 2018'	System	15 Sep 2020 23:51:14

US3822181

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User entered '2018'	System	15 Sep 2020 23:51:14

US3822181

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User entered empty.	System	15 Sep 2020 23:51:14

US3822181

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User entered empty.	System	15 Sep 2020 23:51:14

US3822181

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:56:07

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal vascular conditions, HLT: Haemorrhoids and gastrointestinal varices (excl oesophageal), PT: Haemorrhoids, LLT: Hemorrhoids - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 23:52:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 23:52:46
Data point term sent to Coder	System	15 Sep 2020 23:52:26
User entered 'hemorrhoids'	Kelly Woodell (b) (4)	15 Sep 2020 23:51:32

US3822181

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'un UNK 2020'	Kelly Woodell (b) (4)	15 Sep 2020 23:51:32

US3822181

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:56:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '0'	Kelly Woodell (b) (4)	15 Sep 2020 23:51:32

US3822181

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:56:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	15 Sep 2020 23:51:32

US3822181

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered empty.	Kelly Woodell (b) (4)	15 Sep 2020 23:51:32

US3822181

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:56:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '0'	Kelly Woodell (b) (4)	15 Sep 2020 23:51:32

US3822181

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User entered 'Jan 2020'	System	15 Sep 2020 23:51:32

US3822181

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User entered '2020'	System	15 Sep 2020 23:51:32

US3822181

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User entered empty.	System	15 Sep 2020 23:51:32

US3822181

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User entered empty.	System	15 Sep 2020 23:51:32

US3822181

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:56:07

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 23:52:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 23:52:47
Data point term sent to Coder	System	15 Sep 2020 23:52:26
User entered 'erectile dysfunction'	Kelly Woodell (b) (4)	15 Sep 2020 23:52:00

US3822181

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'un UNK 2020'	Kelly Woodell (b) (4)	15 Sep 2020 23:52:00

US3822181

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:56:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '0'	Kelly Woodell (b) (4)	15 Sep 2020 23:52:00

US3822181

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:56:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	15 Sep 2020 23:52:00

US3822181

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered empty.	Kelly Woodell (b) (4)	15 Sep 2020 23:52:00

US3822181

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:56:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '0'	Kelly Woodell (b) (4)	15 Sep 2020 23:52:00

US3822181

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User entered 'Jan 2020'	System	15 Sep 2020 23:52:00

US3822181

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User entered '2020'	System	15 Sep 2020 23:52:00

US3822181

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User entered empty.	System	15 Sep 2020 23:52:00

US3822181

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User entered empty.	System	15 Sep 2020 23:52:00

US3822181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	15 Sep 2020 23:55:00

US3822181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '19 Aug 2020'	Kelly Woodell (b) (4)	15 Sep 2020 23:55:00

US3822181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '07:45'	Kelly Woodell (b) (4)	15 Sep 2020 23:55:00

US3822181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User entered '19 Aug 2020 07:45'	System	15 Sep 2020 23:55:00

US3822181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '73.1' in	Kelly Woodell (b) (4)	15 Sep 2020 23:55:00
DataPoint set to visible.	System	19 Aug 2020 12:39:25

US3822181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '231.2' lb	Kelly Woodell (b) (4)	15 Sep 2020 23:55:00
DataPoint set to visible.	System	19 Aug 2020 12:39:25

US3822181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User entered '30.48337'	System	15 Sep 2020 23:55:00
DataPoint set to visible.	System	19 Aug 2020 12:39:25

US3822181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User entered 'kg/m2'	System	15 Sep 2020 23:55:00
DataPoint set to visible.	System	19 Aug 2020 12:39:25

US3822181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered missing code ND - Not Done.	Kelly Woodell (b) (4)	15 Sep 2020 23:55:00

US3822181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered empty.	Kelly Woodell (b) (4)	15 Sep 2020 23:55:00

US3822181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered empty.	Kelly Woodell (b) (4)	15 Sep 2020 23:55:00

US3822181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered missing code ND - Not Done.	Kelly Woodell (b) (4)	15 Sep 2020 23:55:00

US3822181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User entered 'bpm'	System	15 Sep 2020 23:55:00

US3822181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered missing code ND - Not Done.	Kelly Woodell (b) (4)	15 Sep 2020 23:55:00

US3822181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User entered 'breaths/min'	System	15 Sep 2020 23:55:00

US3822181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered missing code ND - Not Done.	Kelly Woodell (b) (4)	15 Sep 2020 23:55:00

US3822181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User entered 'mmHg'	System	15 Sep 2020 23:55:00

US3822181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered missing code ND - Not Done.	Kelly Woodell (b) (4)	15 Sep 2020 23:55:00

US3822181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User entered 'mmHg'	System	15 Sep 2020 23:55:00

US3822181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38

US3822181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38

US3822181

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:56:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	15 Sep 2020 23:55:11

US3822181

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:56:07

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '19 Aug 2020'	Kelly Woodell (b) (4)	15 Sep 2020 23:55:11

US3822181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'No (N)'	Kelly Woodell (b) (4)	15 Sep 2020 23:55:33

US3822181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'No (N)'	Kelly Woodell (b) (4)	15 Sep 2020 23:55:33

US3822181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:07

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)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'No (N)'	Kelly Woodell (b) (4)	15 Sep 2020 23:55:33

US3822181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:07

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)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'No (N)'	Kelly Woodell (b) (4)	15 Sep 2020 23:55:33

US3822181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'No (N)'	Kelly Woodell (b) (4)	15 Sep 2020 23:55:33

US3822181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:07

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)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'No (N)'	Kelly Woodell (b) (4)	15 Sep 2020 23:55:33

US3822181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:07

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)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'No (N)'	Kelly Woodell (b) (4)	15 Sep 2020 23:55:33

US3822181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:07

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)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'No (N)'	Kelly Woodell (b) (4)	15 Sep 2020 23:55:33

US3822181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:07

[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)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'No (N)'	Kelly Woodell (b) (4)	15 Sep 2020 23:55:33

US3822181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:07

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)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'No (N)'	Kelly Woodell (b) (4)	15 Sep 2020 23:55:33

US3822181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:07

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)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'No (N)'	Kelly Woodell (b) (4)	15 Sep 2020 23:55:33

US3822181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:07

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'No (N)'	Kelly Woodell (b) (4)	15 Sep 2020 23:55:33

US3822181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:07

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered empty.	Kelly Woodell (b) (4)	15 Sep 2020 23:55:33

US3822181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:07

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '0'	Kelly Woodell (b) (4)	15 Sep 2020 23:55:33

US3822181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '0'	Kelly Woodell (b) (4)	15 Sep 2020 23:55:33

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:07

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)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '0'	Kelly Woodell (b) (4)	15 Sep 2020 23:55:33

US3822181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:07

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)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '1'	Kelly Woodell (b) (4)	15 Sep 2020 23:55:33

US3822181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:07

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)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '0'	Kelly Woodell (b) (4)	15 Sep 2020 23:55:33

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '0'	Kelly Woodell (b) (4)	15 Sep 2020 23:55:33

US3822181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:07

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '0'	Kelly Woodell (b) (4)	15 Sep 2020 23:55:33

US3822181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:07

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered empty.	Kelly Woodell (b) (4)	15 Sep 2020 23:55:33

US3822181

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:56:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	15 Sep 2020 23:55:47

US3822181

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '19 Aug 2020'	Kelly Woodell (b) (4)	15 Sep 2020 23:55:47

US3822181

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Clinic (Clinic)'	Kelly Woodell (b) (4)	15 Sep 2020 23:55:47

US3822181

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:56:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered 'VISIT1'	System	15 Sep 2020 23:55:47

US3822181

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '19 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 11:54:35

US3822181

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:28:53
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:28:53
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 11:54:35
User entered '105714' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 11:54:35

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 11:54:35

US3822181

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:56:07

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)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User closed query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Sep 2020 05:13:25
Query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' answered with 'Completed' (Site from DM).	Kelly Woodell (b) (4) (b) (4)	15 Sep 2020 23:56:04
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	15 Sep 2020 23:55:57
User opened query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 12:12:34
Query 'US3822181 ' canceled (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 12:12:24
User opened query 'US3822181 ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 06:58:18

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:56:07

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)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'No (N)'	Kelly Woodell (b) (4)	15 Sep 2020 23:55:57

US3822181

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'No (N)'	Kelly Woodell (b) (4)	15 Sep 2020 23:55:57

US3822181

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:56:07

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'No (N)'	Kelly Woodell (b) (4)	15 Sep 2020 23:55:57

US3822181

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:56:07

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'No (N)'	Kelly Woodell (b) (4)	15 Sep 2020 23:55:57

US3822181

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:34:35
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:35:28
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:26:59

US3822181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:56:07

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered missing code ND - Not Done.	Kelly Woodell (b) (4)	15 Sep 2020 23:57:15

US3822181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:56:07

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered missing code ND - Not Done.	Kelly Woodell (b) (4)	15 Sep 2020 23:57:15

US3822181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:56:07

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered missing code ND - Not Done.	Kelly Woodell (b) (4)	15 Sep 2020 23:57:15

US3822181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:56:07

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered missing code ND - Not Done.	Kelly Woodell (b) (4)	15 Sep 2020 23:57:15

US3822181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User accepted default value 'Pre-Dose (PREDOSE)'	Kelly Woodell (b) (4) (b) (4)	15 Sep 2020 23:57:15

US3822181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	15 Sep 2020 23:57:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '19 Aug 2020'	Kelly Woodell (b) (4)	15 Sep 2020 23:57:15

US3822181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '07:45'	Kelly Woodell (b) (4)	15 Sep 2020 23:57:15

US3822181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered '19 Aug 2020 07:45'	System	15 Sep 2020 23:57:15

US3822181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '97.9' F	Kelly Woodell (b) (4)	15 Sep 2020 23:57:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Oral (Oral)'	Kelly Woodell (b) (4)	15 Sep 2020 23:57:15

US3822181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered empty.	Kelly Woodell (b) (4)	15 Sep 2020 23:57:15

US3822181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '64'	Kelly Woodell (b) (4)	15 Sep 2020 23:57:15

US3822181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered 'bpm'	System	15 Sep 2020 23:57:15

US3822181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '20'	Kelly Woodell (b) (4)	15 Sep 2020 23:57:15

US3822181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered 'breaths/min'	System	15 Sep 2020 23:57:15

US3822181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '130'	Kelly Woodell (b) (4)	15 Sep 2020 23:57:15

US3822181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered 'mmHg'	System	15 Sep 2020 23:57:15

US3822181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '84'	Kelly Woodell (b) (4)	15 Sep 2020 23:57:15

US3822181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered 'mmHg'	System	15 Sep 2020 23:57:15

US3822181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:56:07

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered missing code ND - Not Done.	Kelly Woodell (b) (4)	15 Sep 2020 23:57:15

US3822181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:56:07

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered missing code ND - Not Done.	Kelly Woodell (b) (4)	15 Sep 2020 23:57:15

US3822181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User accepted default value 'Post-Dose (POSTDOSE)'	Kelly Woodell (b) (4) (b) (4)	15 Sep 2020 23:57:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	15 Sep 2020 23:57:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '19 Aug 2020'	Kelly Woodell (b) (4)	15 Sep 2020 23:57:15

US3822181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '08:57'	Kelly Woodell (b) (4)	15 Sep 2020 23:57:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered '19 Aug 2020 08:57'	System	15 Sep 2020 23:57:15

US3822181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '98.4' F	Kelly Woodell (b) (4)	15 Sep 2020 23:57:15

US3822181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Oral (Oral)'	Kelly Woodell (b) (4)	15 Sep 2020 23:57:15

US3822181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered empty.	Kelly Woodell (b) (4)	15 Sep 2020 23:57:15

US3822181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '74'	Kelly Woodell (b) (4)	15 Sep 2020 23:57:15

US3822181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered 'bpm'	System	15 Sep 2020 23:57:15

US3822181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '20'	Kelly Woodell (b) (4)	15 Sep 2020 23:57:15

US3822181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered 'breaths/min'	System	15 Sep 2020 23:57:15

US3822181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '104'	Kelly Woodell (b) (4)	15 Sep 2020 23:57:15

US3822181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered 'mmHg'	System	15 Sep 2020 23:57:15

US3822181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '78'	Kelly Woodell (b) (4)	15 Sep 2020 23:57:15

US3822181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered 'mmHg'	System	15 Sep 2020 23:57:15

US3822181

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:56:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'No (N)'	Kelly Woodell (b) (4)	15 Sep 2020 23:57:19

US3822181

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:56:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered empty.	Kelly Woodell (b) (4)	15 Sep 2020 23:57:19

US3822181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:56:07

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	19 Aug 2020 12:40:08

US3822181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:56:07

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered empty.	Kelly Woodell (b) (4)	19 Aug 2020 12:40:08

US3822181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:56:07

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)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered empty.	Kelly Woodell (b) (4)	19 Aug 2020 12:40:08

US3822181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:56:07

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered 'MRNA-1273 OR PLACEBO'	System	19 Aug 2020 12:40:08

US3822181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '19 Aug 2020'	Kelly Woodell (b) (4)	19 Aug 2020 12:40:08

US3822181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '08:26'	Kelly Woodell (b) (4)	19 Aug 2020 12:40:08

US3822181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered '19 Aug 2020 08:26'	System	19 Aug 2020 12:40:08

US3822181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Left Arm (LEFT ARM)'	Kelly Woodell (b) (4)	19 Aug 2020 12:40:08

US3822181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered 'ONCE'	System	19 Aug 2020 12:40:08

US3822181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered 'INTRAMUSCULAR'	System	19 Aug 2020 12:40:08

US3822181

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	15 Sep 2020 23:57:32

US3822181

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '19 Aug 2020'	Kelly Woodell (b) (4)	15 Sep 2020 23:57:32

US3822181

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '07:55'	Kelly Woodell (b) (4)	15 Sep 2020 23:57:32

US3822181

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered '19 Aug 2020 07:55'	System	15 Sep 2020 23:57:32

US3822181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:56:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '19 Aug 2020'	Kelly Woodell (b) (4)	15 Sep 2020 23:57:43

US3822181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:56:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kelly Woodell (b) (4)	15 Sep 2020 23:57:43

US3822181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:56:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	15 Sep 2020 23:57:43

US3822181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '08:06'	Kelly Woodell (b) (4)	15 Sep 2020 23:57:43

US3822181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered '19 Aug 2020 08:06'	System	15 Sep 2020 23:57:43

US3822181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:56:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kelly Woodell (b) (4)	15 Sep 2020 23:57:43

US3822181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:56:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'No (N)'	Kelly Woodell (b) (4)	15 Sep 2020 23:57:43

US3822181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:56:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered empty.	Kelly Woodell (b) (4)	15 Sep 2020 23:57:43

US3822181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered empty.	System	15 Sep 2020 23:57:43

US3822181

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	15 Sep 2020 23:57:47

US3822181

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:56:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered '1'	System	15 Sep 2020 23:57:47

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-19T08:47:23', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '3d09df55-b468-4c92-a38f-4b66278a164e' User entered 'Yes (Y)'	System	19 Aug 2020 12:47:49
	System	19 Aug 2020 12:47:49

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-19T08:47:28', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '3d09df55-b468-4c92-a38f-4b66278a164e' User entered '98.4'	System	19 Aug 2020 12:47:49
	System	19 Aug 2020 12:47:49

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-19T08:47:32', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '3d09df55-b468-4c92-a38f-4b66278a164e' User entered 'No (N)'	System	19 Aug 2020 12:47:49
	System	19 Aug 2020 12:47:49

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-19T08:47:36', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '3d09df55-b468-4c92-a38f-4b66278a164e' User entered '19 Aug 2020 08:47'	System	19 Aug 2020 12:47:49
	System	19 Aug 2020 12:47:49

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '19 Aug 2020 08:46'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '19 Aug 2020 11:16'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-19T17:34:22', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '42f976ce-cf1a-4810-af87-255f8485a32e' User entered 'Yes (Y)'	System	19 Aug 2020 21:34:38
	System	19 Aug 2020 21:34:38

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-19T17:34:25', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '42f976ce-cf1a-4810-af87-255f8485a32e' User entered '97.6'	System	19 Aug 2020 21:34:38
	System	19 Aug 2020 21:34:38

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-19T17:34:28', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '42f976ce-cf1a-4810-af87-255f8485a32e'	System	19 Aug 2020 21:34:38
User entered 'No (N)'	System	19 Aug 2020 21:34:38

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-19T17:34:35', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '42f976ce-cf1a-4810-af87-255f8485a32e' User entered '19 Aug 2020 17:34'	System	19 Aug 2020 21:34:38
	System	19 Aug 2020 21:34:38

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '19 Aug 2020 12:11'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered 'Day 2'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:56:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-20T21:06:51', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '5c462bec-acb0-43b0-87be-673367c093a6' User entered 'Yes (Y)'	System	21 Aug 2020 01:07:10
	System	21 Aug 2020 01:07:10

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:56:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-20T21:06:54', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '5c462bec-acb0-43b0-87be-673367c093a6' User entered '97.3'	System	21 Aug 2020 01:07:10
	System	21 Aug 2020 01:07:10

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-20T21:07:05', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '5c462bec-acb0-43b0-87be-673367c093a6' User entered 'No (N)'	System	21 Aug 2020 01:07:10
	System	21 Aug 2020 01:07:10

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:56:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-20T21:07:07', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '5c462bec-acb0-43b0-87be-673367c093a6' User entered '20 Aug 2020 21:07'	System	21 Aug 2020 01:07:10
	System	21 Aug 2020 01:07:10

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered 'Day 3'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:56:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-21T16:47:23', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '273ddd49-22d3-45dc-ac0d-2f79936c5395' User entered 'Yes (Y)'	System	21 Aug 2020 20:47:34
	System	21 Aug 2020 20:47:34

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:56:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-21T16:47:25', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '273ddd49-22d3-45dc-ac0d-2f79936c5395' User entered '97.2'	System	21 Aug 2020 20:47:34
	System	21 Aug 2020 20:47:34

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-21T16:47:27', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '273ddd49-22d3-45dc-ac0d-2f79936c5395'	System	21 Aug 2020 20:47:34
User entered 'No (N)'	System	21 Aug 2020 20:47:34

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:56:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-21T16:47:32', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '273ddd49-22d3-45dc-ac0d-2f79936c5395' User entered '21 Aug 2020 16:47'	System	21 Aug 2020 20:47:34
	System	21 Aug 2020 20:47:34

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered 'Day 4'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:56:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-22T22:27:39', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '96763caf-be8d-45b1-a411-151217e234ac' User entered 'Yes (Y)'	System	23 Aug 2020 02:27:47
	System	23 Aug 2020 02:27:47

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:56:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-22T22:27:42', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '96763caf-be8d-45b1-a411-151217e234ac' User entered '97.2'	System	23 Aug 2020 02:27:47
	System	23 Aug 2020 02:27:47

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-22T22:27:44', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '96763caf-be8d-45b1-a411-151217e234ac'	System	23 Aug 2020 02:27:47
User entered 'No (N)'	System	23 Aug 2020 02:27:47

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:56:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-22T22:27:45', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '96763caf-be8d-45b1-a411-151217e234ac' User entered '22 Aug 2020 22:27'	System	23 Aug 2020 02:27:47
	System	23 Aug 2020 02:27:47

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered 'Day 5'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:56:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-23T19:52:51', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '79dad652-bf73-446c-a202-8ea8b51be2e8' User entered 'Yes (Y)'	System	23 Aug 2020 23:52:59
	System	23 Aug 2020 23:52:59

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:56:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-23T19:52:53', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '79dad652-bf73-446c-a202-8ea8b51be2e8' User entered '98.2'	System	23 Aug 2020 23:52:59
	System	23 Aug 2020 23:52:59

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-23T19:52:55', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '79dad652-bf73-446c-a202-8ea8b51be2e8'	System	23 Aug 2020 23:52:59
User entered 'No (N)'	System	23 Aug 2020 23:52:59

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:56:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-23T19:52:57', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '79dad652-bf73-446c-a202-8ea8b51be2e8'	System	23 Aug 2020 23:52:59
User entered '23 Aug 2020 19:52'	System	23 Aug 2020 23:52:59

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered 'Day 6'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:56:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-24T21:34:13', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'c34b5ac8-2de3-4c3a-923e-a0f9d18491fb' User entered 'Yes (Y)'	System	25 Aug 2020 01:34:24
	System	25 Aug 2020 01:34:24

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:56:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-24T21:34:15', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'c34b5ac8-2de3-4c3a-923e-a0f9d18491fb' User entered '97.1'	System	25 Aug 2020 01:34:24
	System	25 Aug 2020 01:34:24

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-24T21:34:19', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'c34b5ac8-2de3-4c3a-923e-a0f9d18491fb' User entered 'No (N)'	System	25 Aug 2020 01:34:24
	System	25 Aug 2020 01:34:24

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:56:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-24T21:34:21', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'c34b5ac8-2de3-4c3a-923e-a0f9d18491fb' User entered '24 Aug 2020 21:34'	System	25 Aug 2020 01:34:24
	System	25 Aug 2020 01:34:24

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered 'Day 7'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:56:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-26T07:39:57', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '02003499-2dba-4381-97dc-7fa68a6d8a2f' User entered 'Yes (Y)'	System	26 Aug 2020 11:40:07
	System	26 Aug 2020 11:40:07

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:56:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-26T07:40:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '02003499-2dba-4381-97dc-7fa68a6d8a2f' User entered '97.5'	System	26 Aug 2020 11:40:07
	System	26 Aug 2020 11:40:07

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-26T07:40:01', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '02003499-2dba-4381-97dc-7fa68a6d8a2f' User entered 'No (N)'	System	26 Aug 2020 11:40:07
	System	26 Aug 2020 11:40:07

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:56:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-26T07:40:03', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '02003499-2dba-4381-97dc-7fa68a6d8a2f' User entered '26 Aug 2020 07:40'	System	26 Aug 2020 11:40:07
	System	26 Aug 2020 11:40:07

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-19T08:47:43', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'f3a2cb1c-6be6-4450-9edf-30d62a7b299d'	System	19 Aug 2020 12:48:05
User entered 'None (1)'	System	19 Aug 2020 12:48:05

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-19T08:47:50', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'f3a2cb1c-6be6-4450-9edf-30d62a7b299d' User entered 'No (N)'	System	19 Aug 2020 12:48:05
	System	19 Aug 2020 12:48:05

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-19T08:47:53', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'f3a2cb1c-6be6-4450-9edf-30d62a7b299d' User entered 'No (N)'	System	19 Aug 2020 12:48:05
	System	19 Aug 2020 12:48:05

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-19T08:47:58', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'f3a2cb1c-6be6-4450-9edf-30d62a7b299d' User entered 'None (1)'	System	19 Aug 2020 12:48:05
	System	19 Aug 2020 12:48:05

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-19T08:48:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'f3a2cb1c-6be6-4450-9edf-30d62a7b299d' User entered '19 Aug 2020 08:48'	System	19 Aug 2020 12:48:05
	System	19 Aug 2020 12:48:05

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '19 Aug 2020 08:46'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '19 Aug 2020 11:16'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-19T17:35:04', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'f6ccbdf2-1fee-4ba4-8d8f-f260b1026252'	System	19 Aug 2020 21:35:43
User entered 'Does not interfere with activity (2)'	System	19 Aug 2020 21:35:43

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-19T17:35:06', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'f6ccbdf2-1fee-4ba4-8d8f-f260b1026252'	System	19 Aug 2020 21:35:43
User entered 'No (N)'	System	19 Aug 2020 21:35:43

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-19T17:35:26', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'f6ccbdf2-1fee-4ba4-8d8f-f260b1026252'	System	19 Aug 2020 21:35:43
User entered 'No (N)'	System	19 Aug 2020 21:35:43

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-19T17:35:39', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'f6ccbdf2-1fee-4ba4-8d8f-f260b1026252'	System	19 Aug 2020 21:35:43
User entered 'None (1)'	System	19 Aug 2020 21:35:43

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-19T17:35:42', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'f6ccbdf2-1fee-4ba4-8d8f-f260b1026252'	System	19 Aug 2020 21:35:43
User entered '19 Aug 2020 17:35'	System	19 Aug 2020 21:35:43

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '19 Aug 2020 12:11'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered 'Day 2'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-20T21:07:12', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '2eb6276f-6cdb-4aa0-9261-8caf5480e961' User entered 'Does not interfere with activity (2)'	System	21 Aug 2020 01:07:34
	System	21 Aug 2020 01:07:34

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:56:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-20T21:07:19', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '2eb6276f-6cdb-4aa0-9261-8caf5480e961' User entered 'No (N)'	System	21 Aug 2020 01:07:34
	System	21 Aug 2020 01:07:34

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-20T21:07:23', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '2eb6276f-6cdb-4aa0-9261-8caf5480e961'	System	21 Aug 2020 01:07:34
User entered 'No (N)'	System	21 Aug 2020 01:07:34

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-20T21:07:27', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '2eb6276f-6cdb-4aa0-9261-8caf5480e961' User entered 'None (1)'	System	21 Aug 2020 01:07:34
	System	21 Aug 2020 01:07:34

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:56:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-20T21:07:32', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '2eb6276f-6cdb-4aa0-9261-8caf5480e961' User entered '20 Aug 2020 21:07'	System	21 Aug 2020 01:07:34
	System	21 Aug 2020 01:07:34

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered 'Day 3'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-21T16:47:41', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '86651fdd-6d48-464a-ad8d-ce50ecba986c' User entered 'None (1)'	System	21 Aug 2020 20:47:51
	System	21 Aug 2020 20:47:51

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:56:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-21T16:47:44', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '86651fdd-6d48-464a-ad8d-ce50ecba986c' User entered 'No (N)'	System	21 Aug 2020 20:47:51
	System	21 Aug 2020 20:47:51

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-21T16:47:45', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '86651fdd-6d48-464a-ad8d-ce50ecba986c' User entered 'No (N)'	System	21 Aug 2020 20:47:51
	System	21 Aug 2020 20:47:51

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-21T16:47:47', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '86651fdd-6d48-464a-ad8d-ce50ecba986c' User entered 'None (1)'	System	21 Aug 2020 20:47:51
	System	21 Aug 2020 20:47:51

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:56:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-21T16:47:49', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '86651fdd-6d48-464a-ad8d-ce50ecba986c' User entered '21 Aug 2020 16:47'	System	21 Aug 2020 20:47:51
	System	21 Aug 2020 20:47:51

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered 'Day 4'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-22T22:27:48', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '62509a4a-182c-42da-89e5-4457f8f92025' User entered 'None (1)'	System	23 Aug 2020 02:27:59
	System	23 Aug 2020 02:27:59

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:56:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-22T22:27:50', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '62509a4a-182c-42da-89e5-4457f8f92025' User entered 'No (N)'	System	23 Aug 2020 02:27:59
	System	23 Aug 2020 02:27:59

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-22T22:27:51', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '62509a4a-182c-42da-89e5-4457f8f92025' User entered 'No (N)'	System	23 Aug 2020 02:27:59
	System	23 Aug 2020 02:27:59

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-22T22:27:53', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '62509a4a-182c-42da-89e5-4457f8f92025' User entered 'None (1)'	System	23 Aug 2020 02:27:59
	System	23 Aug 2020 02:27:59

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:56:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-22T22:27:55', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '62509a4a-182c-42da-89e5-4457f8f92025' User entered '22 Aug 2020 22:27'	System	23 Aug 2020 02:27:59
	System	23 Aug 2020 02:27:59

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered 'Day 5'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-23T19:53:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'fc53f02b-6fb0-4b17-b95e-03fb8c4a3e0b' User entered 'None (1)'	System	23 Aug 2020 23:53:09
	System	23 Aug 2020 23:53:09

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:56:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-23T19:53:01', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'fc53f02b-6fb0-4b17-b95e-03fb8c4a3e0b' User entered 'No (N)'	System	23 Aug 2020 23:53:09
	System	23 Aug 2020 23:53:09

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-23T19:53:03', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'fc53f02b-6fb0-4b17-b95e-03fb8c4a3e0b' User entered 'No (N)'	System	23 Aug 2020 23:53:09
	System	23 Aug 2020 23:53:09

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-23T19:53:06', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'fc53f02b-6fb0-4b17-b95e-03fb8c4a3e0b' User entered 'None (1)'	System	23 Aug 2020 23:53:09
	System	23 Aug 2020 23:53:09

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:56:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-23T19:53:08', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'fc53f02b-6fb0-4b17-b95e-03fb8c4a3e0b' User entered '23 Aug 2020 19:53'	System	23 Aug 2020 23:53:09
	System	23 Aug 2020 23:53:09

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered 'Day 6'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-24T21:34:24', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '766077ea-125e-435b-ab29-5700b9e8f4e8' User entered 'None (1)'	System	25 Aug 2020 01:34:33
	System	25 Aug 2020 01:34:33

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:56:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-24T21:34:25', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '766077ea-125e-435b-ab29-5700b9e8f4e8' User entered 'No (N)'	System	25 Aug 2020 01:34:33
	System	25 Aug 2020 01:34:33

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-24T21:34:26', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '766077ea-125e-435b-ab29-5700b9e8f4e8' User entered 'No (N)'	System	25 Aug 2020 01:34:33
	System	25 Aug 2020 01:34:33

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-24T21:34:28', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '766077ea-125e-435b-ab29-5700b9e8f4e8' User entered 'None (1)'	System	25 Aug 2020 01:34:33
	System	25 Aug 2020 01:34:33

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:56:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-24T21:34:30', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '766077ea-125e-435b-ab29-5700b9e8f4e8' User entered '24 Aug 2020 21:34'	System	25 Aug 2020 01:34:33
	System	25 Aug 2020 01:34:33

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered 'Day 7'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-26T07:40:06', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '64b6a1c6-5fa3-44dd-81ef-26185e18eed9' User entered 'None (1)'	System	26 Aug 2020 11:40:17
	System	26 Aug 2020 11:40:17

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:56:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-26T07:40:08', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '64b6a1c6-5fa3-44dd-81ef-26185e18eed9' User entered 'No (N)'	System	26 Aug 2020 11:40:17
	System	26 Aug 2020 11:40:17

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-26T07:40:09', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '64b6a1c6-5fa3-44dd-81ef-26185e18eed9' User entered 'No (N)'	System	26 Aug 2020 11:40:17
	System	26 Aug 2020 11:40:17

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-26T07:40:11', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '64b6a1c6-5fa3-44dd-81ef-26185e18eed9' User entered 'None (1)'	System	26 Aug 2020 11:40:17
	System	26 Aug 2020 11:40:17

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:56:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-26T07:40:12', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '64b6a1c6-5fa3-44dd-81ef-26185e18eed9' User entered '26 Aug 2020 07:40'	System	26 Aug 2020 11:40:17
	System	26 Aug 2020 11:40:17

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-19T08:48:03', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '6a1a638c-474b-4b36-944c-540ece434aea' User entered 'None (0)'	System	19 Aug 2020 12:48:31
	System	19 Aug 2020 12:48:31

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-19T08:48:11', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '6a1a638c-474b-4b36-944c-540ece434aea' User entered 'None (0)'	System	19 Aug 2020 12:48:31
	System	19 Aug 2020 12:48:31

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-19T08:48:14', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '6a1a638c-474b-4b36-944c-540ece434aea' User entered 'None (0)'	System	19 Aug 2020 12:48:31
	System	19 Aug 2020 12:48:31

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-19T08:48:16', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '6a1a638c-474b-4b36-944c-540ece434aea' User entered 'None (0)'	System	19 Aug 2020 12:48:31
	System	19 Aug 2020 12:48:31

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-19T08:48:18', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '6a1a638c-474b-4b36-944c-540ece434aea' User entered 'None (0)'	System	19 Aug 2020 12:48:31
	System	19 Aug 2020 12:48:31

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-19T08:48:19', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '6a1a638c-474b-4b36-944c-540ece434aea' User entered 'None (0)'	System	19 Aug 2020 12:48:31
	System	19 Aug 2020 12:48:31

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-19T08:48:26', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '6a1a638c-474b-4b36-944c-540ece434aea' User entered 'No (N)'	System	19 Aug 2020 12:48:31
	System	19 Aug 2020 12:48:31

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-19T08:48:28', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '6a1a638c-474b-4b36-944c-540ece434aea' User entered '19 Aug 2020 08:48'	System	19 Aug 2020 12:48:31
	System	19 Aug 2020 12:48:31

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '19 Aug 2020 08:46'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '19 Aug 2020 11:16'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-19T17:35:45', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '7068e209-5a59-425d-88a6-c39040951b08'	System	19 Aug 2020 21:36:01
User entered 'None (0)'	System	19 Aug 2020 21:36:01

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-19T17:35:46', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '7068e209-5a59-425d-88a6-c39040951b08'	System	19 Aug 2020 21:36:01
User entered 'None (0)'	System	19 Aug 2020 21:36:01

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-19T17:35:48', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '7068e209-5a59-425d-88a6-c39040951b08'	System	19 Aug 2020 21:36:01
User entered 'None (0)'	System	19 Aug 2020 21:36:01

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-19T17:35:51', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '7068e209-5a59-425d-88a6-c39040951b08'	System	19 Aug 2020 21:36:01
User entered 'None (0)'	System	19 Aug 2020 21:36:01

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-19T17:35:52', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '7068e209-5a59-425d-88a6-c39040951b08'	System	19 Aug 2020 21:36:01
User entered 'None (0)'	System	19 Aug 2020 21:36:01

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-19T17:35:53', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '7068e209-5a59-425d-88a6-c39040951b08'	System	19 Aug 2020 21:36:01
User entered 'None (0)'	System	19 Aug 2020 21:36:01

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-19T17:35:55', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '7068e209-5a59-425d-88a6-c39040951b08'	System	19 Aug 2020 21:36:01
User entered 'No (N)'	System	19 Aug 2020 21:36:01

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-19T17:35:58', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '7068e209-5a59-425d-88a6-c39040951b08'	System	19 Aug 2020 21:36:01
User entered '19 Aug 2020 17:35'	System	19 Aug 2020 21:36:01

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '19 Aug 2020 12:11'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered 'Day 2'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:56:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-20T21:07:35', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '0279e25a-1508-4de0-a652-f5b44fdee5bf' User entered 'None (0)'	System	21 Aug 2020 01:07:50
	System	21 Aug 2020 01:07:50

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:56:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-20T21:07:36', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '0279e25a-1508-4de0-a652-f5b44fdee5bf' User entered 'None (0)'	System	21 Aug 2020 01:07:50
	System	21 Aug 2020 01:07:50

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:56:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-20T21:07:37', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '0279e25a-1508-4de0-a652-f5b44fdee5bf' User entered 'None (0)'	System	21 Aug 2020 01:07:50
	System	21 Aug 2020 01:07:50

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:56:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-20T21:07:38', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '0279e25a-1508-4de0-a652-f5b44fdee5bf' User entered 'None (0)'	System	21 Aug 2020 01:07:50
	System	21 Aug 2020 01:07:50

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:56:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-20T21:07:40', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '0279e25a-1508-4de0-a652-f5b44fdee5bf' User entered 'None (0)'	System	21 Aug 2020 01:07:50
	System	21 Aug 2020 01:07:50

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:56:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-20T21:07:41', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '0279e25a-1508-4de0-a652-f5b44fdee5bf' User entered 'None (0)'	System	21 Aug 2020 01:07:50
	System	21 Aug 2020 01:07:50

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-20T21:07:46', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '0279e25a-1508-4de0-a652-f5b44fdee5bf' User entered 'No (N)'	System	21 Aug 2020 01:07:50
	System	21 Aug 2020 01:07:50

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:56:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-20T21:07:48', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '0279e25a-1508-4de0-a652-f5b44fdee5bf' User entered '20 Aug 2020 21:07'	System	21 Aug 2020 01:07:50
	System	21 Aug 2020 01:07:50

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered 'Day 3'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:56:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-21T16:47:53', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '07955e37-84d7-4dd8-9e8d-618c2f138405' User entered 'None (0)'	System	21 Aug 2020 20:48:07
	System	21 Aug 2020 20:48:07

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:56:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-21T16:47:54', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '07955e37-84d7-4dd8-9e8d-618c2f138405' User entered 'None (0)'	System	21 Aug 2020 20:48:07
	System	21 Aug 2020 20:48:07

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:56:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-21T16:47:56', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '07955e37-84d7-4dd8-9e8d-618c2f138405' User entered 'None (0)'	System	21 Aug 2020 20:48:07
	System	21 Aug 2020 20:48:07

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:56:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-21T16:47:57', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '07955e37-84d7-4dd8-9e8d-618c2f138405' User entered 'None (0)'	System	21 Aug 2020 20:48:07
	System	21 Aug 2020 20:48:07

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:56:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-21T16:47:59', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '07955e37-84d7-4dd8-9e8d-618c2f138405' User entered 'None (0)'	System	21 Aug 2020 20:48:07
	System	21 Aug 2020 20:48:07

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:56:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-21T16:48:01', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '07955e37-84d7-4dd8-9e8d-618c2f138405' User entered 'None (0)'	System	21 Aug 2020 20:48:07
	System	21 Aug 2020 20:48:07

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-21T16:48:03', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '07955e37-84d7-4dd8-9e8d-618c2f138405' User entered 'No (N)'	System	21 Aug 2020 20:48:07
	System	21 Aug 2020 20:48:07

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:56:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-21T16:48:05', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '07955e37-84d7-4dd8-9e8d-618c2f138405' User entered '21 Aug 2020 16:48'	System	21 Aug 2020 20:48:07
	System	21 Aug 2020 20:48:07

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered 'Day 4'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:56:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-22T22:28:02', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '273e345b-c495-4aeb-a633-b535b1b3efee' User entered 'None (0)'	System	23 Aug 2020 02:28:17
	System	23 Aug 2020 02:28:17

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:56:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-22T22:28:04', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '273e345b-c495-4aeb-a633-b535b1b3efee' User entered 'None (0)'	System	23 Aug 2020 02:28:17
	System	23 Aug 2020 02:28:17

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:56:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-22T22:28:06', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '273e345b-c495-4aeb-a633-b535b1b3efee' User entered 'None (0)'	System	23 Aug 2020 02:28:17
	System	23 Aug 2020 02:28:17

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:56:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-22T22:28:08', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '273e345b-c495-4aeb-a633-b535b1b3efee' User entered 'None (0)'	System	23 Aug 2020 02:28:17
	System	23 Aug 2020 02:28:17

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:56:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-22T22:28:10', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '273e345b-c495-4aeb-a633-b535b1b3efee' User entered 'None (0)'	System	23 Aug 2020 02:28:17
	System	23 Aug 2020 02:28:17

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:56:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-22T22:28:11', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '273e345b-c495-4aeb-a633-b535b1b3efee' User entered 'None (0)'	System	23 Aug 2020 02:28:17
	System	23 Aug 2020 02:28:17

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-22T22:28:13', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '273e345b-c495-4aeb-a633-b535b1b3efee' User entered 'No (N)'	System	23 Aug 2020 02:28:17
	System	23 Aug 2020 02:28:17

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:56:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-22T22:28:15', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '273e345b-c495-4aeb-a633-b535b1b3efee' User entered '22 Aug 2020 22:28'	System	23 Aug 2020 02:28:17
	System	23 Aug 2020 02:28:17

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered 'Day 5'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:56:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-23T19:53:13', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'c339d1af-63dd-4b4f-a857-64360fc49d41' User entered 'None (0)'	System	23 Aug 2020 23:53:30
	System	23 Aug 2020 23:53:30

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:56:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-23T19:53:15', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'c339d1af-63dd-4b4f-a857-64360fc49d41' User entered 'None (0)'	System	23 Aug 2020 23:53:30
	System	23 Aug 2020 23:53:30

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:56:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-23T19:53:17', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'c339d1af-63dd-4b4f-a857-64360fc49d41' User entered 'None (0)'	System	23 Aug 2020 23:53:30
	System	23 Aug 2020 23:53:30

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:56:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-23T19:53:19', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'c339d1af-63dd-4b4f-a857-64360fc49d41' User entered 'None (0)'	System	23 Aug 2020 23:53:30
	System	23 Aug 2020 23:53:30

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:56:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-23T19:53:21', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'c339d1af-63dd-4b4f-a857-64360fc49d41' User entered 'None (0)'	System	23 Aug 2020 23:53:30
	System	23 Aug 2020 23:53:30

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:56:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-23T19:53:22', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'c339d1af-63dd-4b4f-a857-64360fc49d41' User entered 'None (0)'	System	23 Aug 2020 23:53:30
	System	23 Aug 2020 23:53:30

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-23T19:53:26', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'c339d1af-63dd-4b4f-a857-64360fc49d41'	System	23 Aug 2020 23:53:30
User entered 'No (N)'	System	23 Aug 2020 23:53:30

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:56:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-23T19:53:27', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'c339d1af-63dd-4b4f-a857-64360fc49d41' User entered '23 Aug 2020 19:53'	System	23 Aug 2020 23:53:30
	System	23 Aug 2020 23:53:30

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered 'Day 6'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:56:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-24T21:34:33', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '2ee86f37-5f51-4e59-8c17-8b143293c2bb' User entered 'None (0)'	System	25 Aug 2020 01:34:50
	System	25 Aug 2020 01:34:50

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:56:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-24T21:34:34', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '2ee86f37-5f51-4e59-8c17-8b143293c2bb' User entered 'None (0)'	System	25 Aug 2020 01:34:50
	System	25 Aug 2020 01:34:50

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:56:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-24T21:34:36', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '2ee86f37-5f51-4e59-8c17-8b143293c2bb' User entered 'None (0)'	System	25 Aug 2020 01:34:50
	System	25 Aug 2020 01:34:50

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:56:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-24T21:34:37', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '2ee86f37-5f51-4e59-8c17-8b143293c2bb' User entered 'None (0)'	System	25 Aug 2020 01:34:50
	System	25 Aug 2020 01:34:50

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:56:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-24T21:34:39', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '2ee86f37-5f51-4e59-8c17-8b143293c2bb' User entered 'None (0)'	System	25 Aug 2020 01:34:50
	System	25 Aug 2020 01:34:50

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:56:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-24T21:34:40', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '2ee86f37-5f51-4e59-8c17-8b143293c2bb' User entered 'None (0)'	System	25 Aug 2020 01:34:50
	System	25 Aug 2020 01:34:50

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-24T21:34:42', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '2ee86f37-5f51-4e59-8c17-8b143293c2bb' User entered 'No (N)'	System	25 Aug 2020 01:34:50
	System	25 Aug 2020 01:34:50

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:56:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-24T21:34:44', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '2ee86f37-5f51-4e59-8c17-8b143293c2bb' User entered '24 Aug 2020 21:34'	System	25 Aug 2020 01:34:50
	System	25 Aug 2020 01:34:50

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered 'Day 7'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:56:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-26T07:40:17', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '0ef21d7d-fae2-481c-97a6-566c64a5e4d1' User entered 'None (0)'	System	26 Aug 2020 11:40:34
	System	26 Aug 2020 11:40:34

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:56:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-26T07:40:18', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '0ef21d7d-fae2-481c-97a6-566c64a5e4d1' User entered 'None (0)'	System	26 Aug 2020 11:40:34
	System	26 Aug 2020 11:40:34

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:56:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-26T07:40:20', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '0ef21d7d-fae2-481c-97a6-566c64a5e4d1' User entered 'None (0)'	System	26 Aug 2020 11:40:34
	System	26 Aug 2020 11:40:34

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:56:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-26T07:40:21', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '0ef21d7d-fae2-481c-97a6-566c64a5e4d1' User entered 'None (0)'	System	26 Aug 2020 11:40:34
	System	26 Aug 2020 11:40:34

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:56:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-26T07:40:23', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '0ef21d7d-fae2-481c-97a6-566c64a5e4d1' User entered 'None (0)'	System	26 Aug 2020 11:40:34
	System	26 Aug 2020 11:40:34

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:56:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-26T07:40:25', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '0ef21d7d-fae2-481c-97a6-566c64a5e4d1' User entered 'None (0)'	System	26 Aug 2020 11:40:34
	System	26 Aug 2020 11:40:34

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-26T07:40:29', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '0ef21d7d-fae2-481c-97a6-566c64a5e4d1' User entered 'No (N)'	System	26 Aug 2020 11:40:34
	System	26 Aug 2020 11:40:34

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:56:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-08-26T07:40:31', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '0ef21d7d-fae2-481c-97a6-566c64a5e4d1' User entered '26 Aug 2020 07:40'	System	26 Aug 2020 11:40:34
	System	26 Aug 2020 11:40:34

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 12:40:08

US3822181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 12:40:08

US3822181

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	15 Sep 2020 23:58:38

US3822181

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '27 Aug 2020'	Kelly Woodell (b) (4)	15 Sep 2020 23:58:38

US3822181

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Contact Made (CONTACT MADE)'	Kelly Woodell (b) (4)	15 Sep 2020 23:58:38

US3822181

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered empty.	Kelly Woodell (b) (4)	15 Sep 2020 23:58:38

US3822181

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	15 Sep 2020 23:58:45

US3822181

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered '1'	System	15 Sep 2020 23:58:45

US3822181

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	15 Sep 2020 23:59:00

US3822181

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '3 Sep 2020'	Kelly Woodell (b) (4)	15 Sep 2020 23:59:00

US3822181

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Contact Made (CONTACT MADE)'	Kelly Woodell (b) (4)	15 Sep 2020 23:59:00

US3822181

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered empty.	Kelly Woodell (b) (4)	15 Sep 2020 23:59:00

US3822181

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	15 Sep 2020 23:59:07

US3822181

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered '1'	System	15 Sep 2020 23:59:07

US3822181

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	15 Sep 2020 23:59:24

US3822181

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '10 Sep 2020'	Kelly Woodell (b) (4)	15 Sep 2020 23:59:24

US3822181

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Contact Made (CONTACT MADE)'	Kelly Woodell (b) (4)	15 Sep 2020 23:59:24

US3822181

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered empty.	Kelly Woodell (b) (4)	15 Sep 2020 23:59:24

US3822181

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	15 Sep 2020 23:59:44

US3822181

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered '1'	System	15 Sep 2020 23:59:44

US3822181

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	24 Sep 2020 12:04:15

US3822181

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:07

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 11:24:42
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Date is correct as is' (Site from System).	Kelly Woodell (b) (4) (b) (4)	24 Sep 2020 12:04:30
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	24 Sep 2020 12:04:15
User entered '24 Sep 2020'	Kelly Woodell (b) (4) (b) (4)	24 Sep 2020 12:04:15

US3822181

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered 'Clinic (Clinic)'	Kelly Woodell (b) (4)	24 Sep 2020 12:04:15

US3822181

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered 'VISIT2'	System	24 Sep 2020 12:04:15

US3822181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	19 Oct 2020 12:35:52

US3822181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:35:52

US3822181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:35:52

US3822181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered '07:19'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:35:52

US3822181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered '24 Sep 2020 07:19'	System	19 Oct 2020 12:35:52

US3822181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:35:52

US3822181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:35:52

US3822181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:35:52

US3822181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered '72'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:35:52

US3822181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered 'bpm'	System	19 Oct 2020 12:35:52

US3822181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered '16'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:35:52

US3822181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered 'breaths/min'	System	19 Oct 2020 12:35:52

US3822181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered '128'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:35:52

US3822181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered 'mmHg'	System	19 Oct 2020 12:35:52

US3822181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered '78'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:35:52

US3822181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered 'mmHg'	System	19 Oct 2020 12:35:52

US3822181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	19 Oct 2020 12:35:52

US3822181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:35:52

US3822181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:35:52

US3822181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered '08:23'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:35:52

US3822181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered '24 Sep 2020 08:23'	System	19 Oct 2020 12:35:52

US3822181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:35:52

US3822181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:35:52

US3822181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:35:52

US3822181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered '69'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:35:52

US3822181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered 'bpm'	System	19 Oct 2020 12:35:52

US3822181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered '17'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:35:52

US3822181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered 'breaths/min'	System	19 Oct 2020 12:35:52

US3822181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered '130'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:35:52

US3822181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered 'mmHg'	System	19 Oct 2020 12:35:52

US3822181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered '74'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:35:52

US3822181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered 'mmHg'	System	19 Oct 2020 12:35:52

US3822181

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:56:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'No (N)'	Kelly Woodell (b) (4)	24 Sep 2020 12:04:35

US3822181

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:56:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered empty.	Kelly Woodell (b) (4)	24 Sep 2020 12:04:35

US3822181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:56:07

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	24 Sep 2020 12:05:09

US3822181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:56:07

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered empty.	Kelly Woodell (b) (4)	24 Sep 2020 12:05:09

US3822181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:56:07

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)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered empty.	Kelly Woodell (b) (4)	24 Sep 2020 12:05:09

US3822181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:56:07

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered 'MRNA-1273 OR PLACEBO'	System	24 Sep 2020 12:05:09

US3822181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:56:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '24 Sep 2020'	Kelly Woodell (b) (4)	24 Sep 2020 12:05:09

US3822181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:56:07

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '07:53'	Kelly Woodell (b) (4)	24 Sep 2020 12:05:09

US3822181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:56:07

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered '24 Sep 2020 07:53'	System	24 Sep 2020 12:05:09

US3822181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:56:07

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Left Arm (LEFT ARM)'	Kelly Woodell (b) (4)	24 Sep 2020 12:05:09

US3822181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:56:07

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered 'ONCE'	System	24 Sep 2020 12:05:09

US3822181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:56:07

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered 'INTRAMUSCULAR'	System	24 Sep 2020 12:05:09

US3822181

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	24 Sep 2020 12:05:28

US3822181

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '24 Sep 2020'	Kelly Woodell (b) (4)	24 Sep 2020 12:05:28

US3822181

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '07:29'	Kelly Woodell (b) (4)	24 Sep 2020 12:05:28

US3822181

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered '24 Sep 2020 07:29'	System	24 Sep 2020 12:05:28

US3822181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:56:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '24 Sep 2020'	Kelly Woodell (b) (4)	24 Sep 2020 12:05:58

US3822181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:56:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kelly Woodell (b) (4)	24 Sep 2020 12:05:58

US3822181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:56:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	24 Sep 2020 12:05:58

US3822181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:56:07

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '07:33'	Kelly Woodell (b) (4)	24 Sep 2020 12:05:58

US3822181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:56:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered '24 Sep 2020 07:33'	System	24 Sep 2020 12:05:58

US3822181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:56:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kelly Woodell (b) (4)	24 Sep 2020 12:05:58

US3822181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:56:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'No (N)'	Kelly Woodell (b) (4)	24 Sep 2020 12:05:58

US3822181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:56:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered empty.	Kelly Woodell (b) (4)	24 Sep 2020 12:05:58

US3822181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:56:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered empty.	System	24 Sep 2020 12:05:58

US3822181

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	24 Sep 2020 12:06:03

US3822181

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered '1'	System	24 Sep 2020 12:06:03

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	24 Sep 2020 12:05:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-24T08:16:05', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'a36da47c-acf5-413a-9653-383de370774d' User entered 'Yes (Y)'	System	24 Sep 2020 12:16:26
	System	24 Sep 2020 12:16:26

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-24T08:16:09', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'a36da47c-acf5-413a-9653-383de370774d' User entered '98.7'	System	24 Sep 2020 12:16:26
	System	24 Sep 2020 12:16:26

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-24T08:16:11', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'a36da47c-acf5-413a-9653-383de370774d' User entered 'No (N)'	System	24 Sep 2020 12:16:26
	System	24 Sep 2020 12:16:26

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-24T08:16:13', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'a36da47c-acf5-413a-9653-383de370774d' User entered '24 Sep 2020 08:16'	System	24 Sep 2020 12:16:26
	System	24 Sep 2020 12:16:26

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '24 Sep 2020 08:13'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '24 Sep 2020 10:43'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	24 Sep 2020 12:05:09
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-24T21:42:01', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '3084614d-0e99-4c77-a278-dd88ed922f00' User entered 'Yes (Y)'	System	25 Sep 2020 01:43:06
	System	25 Sep 2020 01:43:06

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-24T21:42:04', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '3084614d-0e99-4c77-a278-dd88ed922f00' User entered '97.2'	System	25 Sep 2020 01:43:06
	System	25 Sep 2020 01:43:06

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-24T21:42:51', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '3084614d-0e99-4c77-a278-dd88ed922f00'	System	25 Sep 2020 01:43:06
User entered 'No (N)'	System	25 Sep 2020 01:43:06

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-24T21:43:01', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '3084614d-0e99-4c77-a278-dd88ed922f00'	System	25 Sep 2020 01:43:06
User entered '24 Sep 2020 21:43'	System	25 Sep 2020 01:43:06

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '24 Sep 2020 11:38'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	24 Sep 2020 12:05:09
User entered 'Day 2'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:56:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-25T18:50:47', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '482ed36f-620c-4124-9877-ba272a1d4b05' User entered 'Yes (Y)'	System	25 Sep 2020 22:51:07
	System	25 Sep 2020 22:51:07

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:56:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-25T18:50:50', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '482ed36f-620c-4124-9877-ba272a1d4b05' User entered '98.1'	System	25 Sep 2020 22:51:07
	System	25 Sep 2020 22:51:07

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:56:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-25T18:50:56', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '482ed36f-620c-4124-9877-ba272a1d4b05' User entered 'Yes (Y)'	System	25 Sep 2020 22:51:07
	System	25 Sep 2020 22:51:07

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:56:07

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
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 'updated conmed' (Site from System).	(b) (4), (b) (6)	18 Nov 2020 05:47:05
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.'	Krishna Shah (b) (4)	09 Nov 2020 21:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-25T18:51:03', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '482ed36f-620c-4124-9877-ba272a1d4b05'	(b) (4)	
User entered '1'	System	25 Sep 2020 22:51:07

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:56:07

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-25T18:51:03', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '482ed36f-620c-4124-9877-ba272a1d4b05' User entered '0'	System	25 Sep 2020 22:51:07
	System	25 Sep 2020 22:51:07

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:56:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-25T18:51:05', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '482ed36f-620c-4124-9877-ba272a1d4b05' User entered '25 Sep 2020 18:51'	System	25 Sep 2020 22:51:07
	System	25 Sep 2020 22:51:07

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	24 Sep 2020 12:05:09
User entered 'Day 3'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:56:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-27T09:16:35', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'aa84847c-5fe8-4d0a-9b95-d333b814771d' User entered 'Yes (Y)'	System	27 Sep 2020 13:16:44
	System	27 Sep 2020 13:16:44

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:56:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-27T09:16:38', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'aa84847c-5fe8-4d0a-9b95-d333b814771d' User entered '98.1'	System	27 Sep 2020 13:16:44
	System	27 Sep 2020 13:16:44

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:56:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-27T09:16:40', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'aa84847c-5fe8-4d0a-9b95-d333b814771d' User entered 'No (N)'	System	27 Sep 2020 13:16:44
	System	27 Sep 2020 13:16:44

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:56:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-27T09:16:42', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'aa84847c-5fe8-4d0a-9b95-d333b814771d' User entered '27 Sep 2020 09:16'	System	27 Sep 2020 13:16:44
	System	27 Sep 2020 13:16:44

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	24 Sep 2020 12:05:09
User entered 'Day 4'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:56:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-28T10:11:37', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '488215d7-c66e-4546-bde3-db9ec7891011' User entered 'Yes (Y)'	System	28 Sep 2020 14:12:26
	System	28 Sep 2020 14:12:26

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:56:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-28T10:11:41', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '488215d7-c66e-4546-bde3-db9ec7891011' User entered '96.2'	System	28 Sep 2020 14:12:26
	System	28 Sep 2020 14:12:26

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:56:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-28T10:11:43', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '488215d7-c66e-4546-bde3-db9ec7891011' User entered 'No (N)'	System	28 Sep 2020 14:12:26
	System	28 Sep 2020 14:12:26

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:56:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-28T10:12:22', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '488215d7-c66e-4546-bde3-db9ec7891011' User entered '28 Sep 2020 10:12'	System	28 Sep 2020 14:12:26
	System	28 Sep 2020 14:12:26

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	24 Sep 2020 12:05:09
User entered 'Day 5'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:56:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-28T21:03:24', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '84f7827e-c4c8-483c-b92f-77524d10e98f' User entered 'Yes (Y)'	System	29 Sep 2020 01:03:44
	System	29 Sep 2020 01:03:44

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:56:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-28T21:03:27', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '84f7827e-c4c8-483c-b92f-77524d10e98f' User entered '98.4'	System	29 Sep 2020 01:03:44
	System	29 Sep 2020 01:03:44

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:56:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-28T21:03:29', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '84f7827e-c4c8-483c-b92f-77524d10e98f' User entered 'No (N)'	System	29 Sep 2020 01:03:44
	System	29 Sep 2020 01:03:44

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:56:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-28T21:03:30', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '84f7827e-c4c8-483c-b92f-77524d10e98f' User entered '28 Sep 2020 21:03'	System	29 Sep 2020 01:03:44
	System	29 Sep 2020 01:03:44

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	24 Sep 2020 12:05:09
User entered 'Day 6'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:56:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-29T22:05:59', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'c939bef9-2f65-4e57-834b-11e1faf1772e' User entered 'Yes (Y)'	System	30 Sep 2020 02:07:01
	System	30 Sep 2020 02:07:01

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:56:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-29T22:06:54', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'c939bef9-2f65-4e57-834b-11e1faf1772e' User entered '97.5'	System	30 Sep 2020 02:07:01
	System	30 Sep 2020 02:07:01

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:56:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-29T22:06:57', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'c939bef9-2f65-4e57-834b-11e1faf1772e' User entered 'No (N)'	System	30 Sep 2020 02:07:01
	System	30 Sep 2020 02:07:01

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:56:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-29T22:06:58', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'c939bef9-2f65-4e57-834b-11e1faf1772e' User entered '29 Sep 2020 22:06'	System	30 Sep 2020 02:07:01
	System	30 Sep 2020 02:07:01

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	24 Sep 2020 12:05:09
User entered 'Day 7'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:56:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-30T23:10:05', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'a80d996c-ed23-4410-8e1a-0406e7df023b' User entered 'Yes (Y)'	System	01 Oct 2020 03:10:16
	System	01 Oct 2020 03:10:16

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:56:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-30T23:10:09', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'a80d996c-ed23-4410-8e1a-0406e7df023b' User entered '97.7'	System	01 Oct 2020 03:10:16
	System	01 Oct 2020 03:10:16

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:56:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-30T23:10:11', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'a80d996c-ed23-4410-8e1a-0406e7df023b' User entered 'No (N)'	System	01 Oct 2020 03:10:16
	System	01 Oct 2020 03:10:16

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:56:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-30T23:10:13', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'a80d996c-ed23-4410-8e1a-0406e7df023b' User entered '30 Sep 2020 23:10'	System	01 Oct 2020 03:10:16
	System	01 Oct 2020 03:10:16

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	24 Sep 2020 12:05:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-24T08:16:17', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '1f16ca45-b061-4d1f-b7e5-95cf91554b04' User entered 'None (1)'	System	24 Sep 2020 12:16:33
	System	24 Sep 2020 12:16:33

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-24T08:16:23', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '1f16ca45-b061-4d1f-b7e5-95cf91554b04' User entered 'No (N)'	System	24 Sep 2020 12:16:33
	System	24 Sep 2020 12:16:33

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-24T08:16:25', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '1f16ca45-b061-4d1f-b7e5-95cf91554b04' User entered 'No (N)'	System	24 Sep 2020 12:16:33
	System	24 Sep 2020 12:16:33

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-24T08:16:28', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '1f16ca45-b061-4d1f-b7e5-95cf91554b04' User entered 'None (1)'	System	24 Sep 2020 12:16:33
	System	24 Sep 2020 12:16:33

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-24T08:16:30', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '1f16ca45-b061-4d1f-b7e5-95cf91554b04' User entered '24 Sep 2020 08:16'	System	24 Sep 2020 12:16:33
	System	24 Sep 2020 12:16:33

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '24 Sep 2020 08:13'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '24 Sep 2020 10:43'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	24 Sep 2020 12:05:09
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-24T21:43:06', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '8f13bca6-38aa-4078-b8d9-7799be1f58cb' User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 01:43:34
	System	25 Sep 2020 01:43:34

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-24T21:43:07', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '8f13bca6-38aa-4078-b8d9-7799be1f58cb' User entered 'No (N)'	System	25 Sep 2020 01:43:34
	System	25 Sep 2020 01:43:34

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-24T21:43:26', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '8f13bca6-38aa-4078-b8d9-7799be1f58cb' User entered 'No (N)'	System	25 Sep 2020 01:43:34
	System	25 Sep 2020 01:43:34

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-24T21:43:27', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '8f13bca6-38aa-4078-b8d9-7799be1f58cb' User entered 'None (1)'	System	25 Sep 2020 01:43:34
	System	25 Sep 2020 01:43:34

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-24T21:43:29', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '8f13bca6-38aa-4078-b8d9-7799be1f58cb' User entered '24 Sep 2020 21:43'	System	25 Sep 2020 01:43:34
	System	25 Sep 2020 01:43:34

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '24 Sep 2020 11:38'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	24 Sep 2020 12:05:09
User entered 'Day 2'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-25T18:51:12', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'd16bad09-2825-4465-aa0c-e788ee674caf' User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 22:51:27
	System	25 Sep 2020 22:51:27

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:56:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-25T18:51:19', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'd16bad09-2825-4465-aa0c-e788ee674caf' User entered 'No (N)'	System	25 Sep 2020 22:51:27
	System	25 Sep 2020 22:51:27

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:56:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-25T18:51:18', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'd16bad09-2825-4465-aa0c-e788ee674caf' User entered 'No (N)'	System	25 Sep 2020 22:51:27
	System	25 Sep 2020 22:51:27

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-25T18:51:22', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'd16bad09-2825-4465-aa0c-e788ee674caf' User entered 'None (1)'	System	25 Sep 2020 22:51:27
	System	25 Sep 2020 22:51:27

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:56:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-25T18:51:24', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'd16bad09-2825-4465-aa0c-e788ee674caf' User entered '25 Sep 2020 18:51'	System	25 Sep 2020 22:51:27
	System	25 Sep 2020 22:51:27

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	24 Sep 2020 12:05:09
User entered 'Day 3'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-27T09:16:47', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'b087e148-c47c-486d-8009-c533bd8c3699'	System	27 Sep 2020 13:16:54
User entered 'Does not interfere with activity (2)'	System	27 Sep 2020 13:16:54

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:56:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-27T09:16:49', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'b087e148-c47c-486d-8009-c533bd8c3699' User entered 'No (N)'	System	27 Sep 2020 13:16:54
	System	27 Sep 2020 13:16:54

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:56:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-27T09:16:50', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'b087e148-c47c-486d-8009-c533bd8c3699' User entered 'No (N)'	System	27 Sep 2020 13:16:54
	System	27 Sep 2020 13:16:54

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-27T09:16:51', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'b087e148-c47c-486d-8009-c533bd8c3699' User entered 'None (1)'	System	27 Sep 2020 13:16:54
	System	27 Sep 2020 13:16:54

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:56:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-27T09:16:53', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'b087e148-c47c-486d-8009-c533bd8c3699' User entered '27 Sep 2020 09:16'	System	27 Sep 2020 13:16:54
	System	27 Sep 2020 13:16:54

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	24 Sep 2020 12:05:09
User entered 'Day 4'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-28T10:12:29', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'c02bace1-3596-46a4-bb81-8ae004150655' User entered 'None (1)'	System	28 Sep 2020 14:12:36
	System	28 Sep 2020 14:12:36

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:56:07

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-28T10:12:30', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'c02bace1-3596-46a4-bb81-8ae004150655' User entered 'No (N)'	System	28 Sep 2020 14:12:36
	System	28 Sep 2020 14:12:36

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:56:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-28T10:12:31', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'c02bace1-3596-46a4-bb81-8ae004150655' User entered 'No (N)'	System	28 Sep 2020 14:12:36
	System	28 Sep 2020 14:12:36

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-28T10:12:32', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'c02bace1-3596-46a4-bb81-8ae004150655' User entered 'None (1)'	System	28 Sep 2020 14:12:36
	System	28 Sep 2020 14:12:36

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:56:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-28T10:12:34', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'c02bace1-3596-46a4-bb81-8ae004150655' User entered '28 Sep 2020 10:12'	System	28 Sep 2020 14:12:36
	System	28 Sep 2020 14:12:36

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	24 Sep 2020 12:05:09
User entered 'Day 5'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-28T21:03:33', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '8fb706ac-7e49-44ae-a041-e91cacc624a9'	System	29 Sep 2020 01:03:50
User entered 'None (1)'	System	29 Sep 2020 01:03:50

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:56:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-28T21:03:35', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '8fb706ac-7e49-44ae-a041-e91cacc624a9' User entered 'No (N)'	System	29 Sep 2020 01:03:50
	System	29 Sep 2020 01:03:50

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:56:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-28T21:03:36', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '8fb706ac-7e49-44ae-a041-e91cacc624a9' User entered 'No (N)'	System	29 Sep 2020 01:03:50
	System	29 Sep 2020 01:03:50

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-28T21:03:38', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '8fb706ac-7e49-44ae-a041-e91cacc624a9' User entered 'None (1)'	System	29 Sep 2020 01:03:50
	System	29 Sep 2020 01:03:50

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:56:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-28T21:03:40', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '8fb706ac-7e49-44ae-a041-e91cacc624a9' User entered '28 Sep 2020 21:03'	System	29 Sep 2020 01:03:50
	System	29 Sep 2020 01:03:50

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	24 Sep 2020 12:05:09
User entered 'Day 6'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-29T22:04:54', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '54920f91-8785-49f9-97ed-ac92795928a5' User entered 'None (1)'	System	30 Sep 2020 02:05:05
	System	30 Sep 2020 02:05:05

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:56:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-29T22:04:56', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '54920f91-8785-49f9-97ed-ac92795928a5' User entered 'No (N)'	System	30 Sep 2020 02:05:05
	System	30 Sep 2020 02:05:05

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:56:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-29T22:04:57', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '54920f91-8785-49f9-97ed-ac92795928a5' User entered 'No (N)'	System	30 Sep 2020 02:05:05
	System	30 Sep 2020 02:05:05

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-29T22:04:59', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '54920f91-8785-49f9-97ed-ac92795928a5' User entered 'None (1)'	System	30 Sep 2020 02:05:05
	System	30 Sep 2020 02:05:05

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:56:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-29T22:05:01', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '54920f91-8785-49f9-97ed-ac92795928a5' User entered '29 Sep 2020 22:05'	System	30 Sep 2020 02:05:05
	System	30 Sep 2020 02:05:05

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	24 Sep 2020 12:05:09
User entered 'Day 7'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-30T23:10:15', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '341081a2-1212-4789-affa-6b6a7c9de9bd' User entered 'None (1)'	System	01 Oct 2020 03:10:25
	System	01 Oct 2020 03:10:25

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:56:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-30T23:10:18', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '341081a2-1212-4789-affa-6b6a7c9de9bd' User entered 'No (N)'	System	01 Oct 2020 03:10:25
	System	01 Oct 2020 03:10:25

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:56:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-30T23:10:19', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '341081a2-1212-4789-affa-6b6a7c9de9bd' User entered 'No (N)'	System	01 Oct 2020 03:10:25
	System	01 Oct 2020 03:10:25

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-30T23:10:21', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '341081a2-1212-4789-affa-6b6a7c9de9bd' User entered 'None (1)'	System	01 Oct 2020 03:10:25
	System	01 Oct 2020 03:10:25

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:56:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-30T23:10:23', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '341081a2-1212-4789-affa-6b6a7c9de9bd' User entered '30 Sep 2020 23:10'	System	01 Oct 2020 03:10:25
	System	01 Oct 2020 03:10:25

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	24 Sep 2020 12:05:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-24T08:16:33', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '2673c115-44c7-4c40-be5d-6eb0040d8961' User entered 'None (0)'	System	24 Sep 2020 12:16:46
	System	24 Sep 2020 12:16:46

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-24T08:16:35', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '2673c115-44c7-4c40-be5d-6eb0040d8961' User entered 'None (0)'	System	24 Sep 2020 12:16:46
	System	24 Sep 2020 12:16:46

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-24T08:16:36', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '2673c115-44c7-4c40-be5d-6eb0040d8961' User entered 'None (0)'	System	24 Sep 2020 12:16:46
	System	24 Sep 2020 12:16:46

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-24T08:16:37', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '2673c115-44c7-4c40-be5d-6eb0040d8961' User entered 'None (0)'	System	24 Sep 2020 12:16:46
	System	24 Sep 2020 12:16:46

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-24T08:16:38', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '2673c115-44c7-4c40-be5d-6eb0040d8961' User entered 'None (0)'	System	24 Sep 2020 12:16:46
	System	24 Sep 2020 12:16:46

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-24T08:16:40', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '2673c115-44c7-4c40-be5d-6eb0040d8961' User entered 'None (0)'	System	24 Sep 2020 12:16:46
	System	24 Sep 2020 12:16:46

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-24T08:16:41', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '2673c115-44c7-4c40-be5d-6eb0040d8961' User entered 'No (N)'	System	24 Sep 2020 12:16:46
	System	24 Sep 2020 12:16:46

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-24T08:16:43', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '2673c115-44c7-4c40-be5d-6eb0040d8961' User entered '24 Sep 2020 08:16'	System	24 Sep 2020 12:16:46
	System	24 Sep 2020 12:16:46

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '24 Sep 2020 08:13'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '24 Sep 2020 10:43'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	24 Sep 2020 12:05:09
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-24T21:43:31', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '4368670c-6956-467f-960c-b69c9b5d6da7' User entered 'None (0)'	System	25 Sep 2020 01:43:56
	System	25 Sep 2020 01:43:56

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-24T21:43:33', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '4368670c-6956-467f-960c-b69c9b5d6da7' User entered 'None (0)'	System	25 Sep 2020 01:43:56
	System	25 Sep 2020 01:43:56

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-24T21:43:35', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '4368670c-6956-467f-960c-b69c9b5d6da7' User entered 'None (0)'	System	25 Sep 2020 01:43:56
	System	25 Sep 2020 01:43:56

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-24T21:43:36', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '4368670c-6956-467f-960c-b69c9b5d6da7' User entered 'None (0)'	System	25 Sep 2020 01:43:56
	System	25 Sep 2020 01:43:56

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-24T21:43:48', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '4368670c-6956-467f-960c-b69c9b5d6da7' User entered 'None (0)'	System	25 Sep 2020 01:43:56
	System	25 Sep 2020 01:43:56

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-24T21:43:49', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '4368670c-6956-467f-960c-b69c9b5d6da7' User entered 'None (0)'	System	25 Sep 2020 01:43:56
	System	25 Sep 2020 01:43:56

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-24T21:43:51', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '4368670c-6956-467f-960c-b69c9b5d6da7' User entered 'No (N)'	System	25 Sep 2020 01:43:56
	System	25 Sep 2020 01:43:56

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-24T21:43:53', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '4368670c-6956-467f-960c-b69c9b5d6da7' User entered '24 Sep 2020 21:43'	System	25 Sep 2020 01:43:56
	System	25 Sep 2020 01:43:56

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '24 Sep 2020 11:38'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	24 Sep 2020 12:05:09
User entered 'Day 2'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:56:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-25T18:51:32', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '2341f561-9db9-448e-ac3c-70433adc598e'	System	25 Sep 2020 22:52:10
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	25 Sep 2020 22:52:10

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:56:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-25T18:51:38', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '2341f561-9db9-448e-ac3c-70433adc598e'	System	25 Sep 2020 22:52:10
User entered 'No interference with activity (1)'	System	25 Sep 2020 22:52:10

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:56:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-25T18:51:49', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '2341f561-9db9-448e-ac3c-70433adc598e'	System	25 Sep 2020 22:52:10
User entered 'No interference with activity (1)'	System	25 Sep 2020 22:52:10

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:56:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-25T18:51:53', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '2341f561-9db9-448e-ac3c-70433adc598e'	System	25 Sep 2020 22:52:10
User entered 'No interference with activity (1)'	System	25 Sep 2020 22:52:10

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:56:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-25T18:51:56', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '2341f561-9db9-448e-ac3c-70433adc598e' User entered 'None (0)'	System	25 Sep 2020 22:52:10
	System	25 Sep 2020 22:52:10

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:56:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-25T18:52:01', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '2341f561-9db9-448e-ac3c-70433adc598e'	System	25 Sep 2020 22:52:10
User entered 'Some interference with activity not requiring medical attention (2)'	System	25 Sep 2020 22:52:10

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-25T18:52:05', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '2341f561-9db9-448e-ac3c-70433adc598e' User entered 'Yes (Y)'	System	25 Sep 2020 22:52:10
	System	25 Sep 2020 22:52:10

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:56:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-25T18:52:07', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '2341f561-9db9-448e-ac3c-70433adc598e' User entered '25 Sep 2020 18:52'	System	25 Sep 2020 22:52:10
	System	25 Sep 2020 22:52:10

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	24 Sep 2020 12:05:09
User entered 'Day 3'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:56:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-27T09:16:56', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'd1ea658f-a1ff-4921-8ceb-a9a7ee1054bb' User entered 'None (0)'	System	27 Sep 2020 13:17:07
	System	27 Sep 2020 13:17:07

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:56:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-27T09:16:57', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'd1ea658f-a1ff-4921-8ceb-a9a7ee1054bb' User entered 'None (0)'	System	27 Sep 2020 13:17:07
	System	27 Sep 2020 13:17:07

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:56:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-27T09:16:58', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'd1ea658f-a1ff-4921-8ceb-a9a7ee1054bb' User entered 'None (0)'	System	27 Sep 2020 13:17:07
	System	27 Sep 2020 13:17:07

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:56:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-27T09:16:59', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'd1ea658f-a1ff-4921-8ceb-a9a7ee1054bb' User entered 'None (0)'	System	27 Sep 2020 13:17:07
	System	27 Sep 2020 13:17:07

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:56:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-27T09:17:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'd1ea658f-a1ff-4921-8ceb-a9a7ee1054bb' User entered 'None (0)'	System	27 Sep 2020 13:17:07
	System	27 Sep 2020 13:17:07

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:56:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-27T09:17:02', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'd1ea658f-a1ff-4921-8ceb-a9a7ee1054bb' User entered 'None (0)'	System	27 Sep 2020 13:17:07
	System	27 Sep 2020 13:17:07

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-27T09:17:04', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'd1ea658f-a1ff-4921-8ceb-a9a7ee1054bb' User entered 'No (N)'	System	27 Sep 2020 13:17:07
	System	27 Sep 2020 13:17:07

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:56:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-27T09:17:05', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'd1ea658f-a1ff-4921-8ceb-a9a7ee1054bb' User entered '27 Sep 2020 09:17'	System	27 Sep 2020 13:17:07
	System	27 Sep 2020 13:17:07

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	24 Sep 2020 12:05:09
User entered 'Day 4'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:56:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-28T10:12:39', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'beee4f79-5739-4857-8688-3b359e208667' User entered 'None (0)'	System	28 Sep 2020 14:12:50
	System	28 Sep 2020 14:12:50

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:56:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-28T10:12:40', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'beee4f79-5739-4857-8688-3b359e208667' User entered 'None (0)'	System	28 Sep 2020 14:12:50
	System	28 Sep 2020 14:12:50

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:56:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-28T10:12:41', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'beee4f79-5739-4857-8688-3b359e208667' User entered 'None (0)'	System	28 Sep 2020 14:12:50
	System	28 Sep 2020 14:12:50

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:56:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-28T10:12:43', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'beee4f79-5739-4857-8688-3b359e208667' User entered 'None (0)'	System	28 Sep 2020 14:12:50
	System	28 Sep 2020 14:12:50

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:56:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-28T10:12:44', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'beee4f79-5739-4857-8688-3b359e208667' User entered 'None (0)'	System	28 Sep 2020 14:12:50
	System	28 Sep 2020 14:12:50

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:56:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-28T10:12:45', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'beee4f79-5739-4857-8688-3b359e208667' User entered 'None (0)'	System	28 Sep 2020 14:12:50
	System	28 Sep 2020 14:12:50

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-28T10:12:46', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'beee4f79-5739-4857-8688-3b359e208667' User entered 'No (N)'	System	28 Sep 2020 14:12:50
	System	28 Sep 2020 14:12:50

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:56:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-28T10:12:48', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'beee4f79-5739-4857-8688-3b359e208667' User entered '28 Sep 2020 10:12'	System	28 Sep 2020 14:12:50
	System	28 Sep 2020 14:12:50

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	24 Sep 2020 12:05:09
User entered 'Day 5'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:56:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-28T21:03:42', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '910df78e-9af5-4dad-93a9-87fab5015e7e' User entered 'None (0)'	System	29 Sep 2020 01:03:53
	System	29 Sep 2020 01:03:53

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:56:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-28T21:03:44', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '910df78e-9af5-4dad-93a9-87fab5015e7e' User entered 'None (0)'	System	29 Sep 2020 01:03:53
	System	29 Sep 2020 01:03:53

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:56:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-28T21:03:45', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '910df78e-9af5-4dad-93a9-87fab5015e7e' User entered 'None (0)'	System	29 Sep 2020 01:03:53
	System	29 Sep 2020 01:03:53

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:56:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-28T21:03:46', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '910df78e-9af5-4dad-93a9-87fab5015e7e' User entered 'None (0)'	System	29 Sep 2020 01:03:53
	System	29 Sep 2020 01:03:53

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:56:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-28T21:03:47', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '910df78e-9af5-4dad-93a9-87fab5015e7e' User entered 'None (0)'	System	29 Sep 2020 01:03:53
	System	29 Sep 2020 01:03:53

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:56:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-28T21:03:48', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '910df78e-9af5-4dad-93a9-87fab5015e7e' User entered 'None (0)'	System	29 Sep 2020 01:03:53
	System	29 Sep 2020 01:03:53

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-28T21:03:49', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '910df78e-9af5-4dad-93a9-87fab5015e7e' User entered 'No (N)'	System	29 Sep 2020 01:03:53
	System	29 Sep 2020 01:03:53

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:56:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-28T21:03:50', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '910df78e-9af5-4dad-93a9-87fab5015e7e' User entered '28 Sep 2020 21:03'	System	29 Sep 2020 01:03:53
	System	29 Sep 2020 01:03:53

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	24 Sep 2020 12:05:09
User entered 'Day 6'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:56:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-29T22:05:04', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '3bd5adbd-b5e5-484f-bd39-53678e180eb0' User entered 'None (0)'	System	30 Sep 2020 02:05:18
	System	30 Sep 2020 02:05:18

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:56:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-29T22:05:05', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '3bd5adbd-b5e5-484f-bd39-53678e180eb0' User entered 'None (0)'	System	30 Sep 2020 02:05:18
	System	30 Sep 2020 02:05:18

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:56:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-29T22:05:07', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '3bd5adbd-b5e5-484f-bd39-53678e180eb0' User entered 'None (0)'	System	30 Sep 2020 02:05:18
	System	30 Sep 2020 02:05:18

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:56:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-29T22:05:09', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '3bd5adbd-b5e5-484f-bd39-53678e180eb0' User entered 'None (0)'	System	30 Sep 2020 02:05:18
	System	30 Sep 2020 02:05:18

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:56:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-29T22:05:10', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '3bd5adbd-b5e5-484f-bd39-53678e180eb0' User entered 'None (0)'	System	30 Sep 2020 02:05:18
	System	30 Sep 2020 02:05:18

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:56:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-29T22:05:11', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '3bd5adbd-b5e5-484f-bd39-53678e180eb0' User entered 'None (0)'	System	30 Sep 2020 02:05:18
	System	30 Sep 2020 02:05:18

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-29T22:05:13', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '3bd5adbd-b5e5-484f-bd39-53678e180eb0' User entered 'No (N)'	System	30 Sep 2020 02:05:18
	System	30 Sep 2020 02:05:18

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:56:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-29T22:05:16', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '3bd5adbd-b5e5-484f-bd39-53678e180eb0' User entered '29 Sep 2020 22:05'	System	30 Sep 2020 02:05:18
	System	30 Sep 2020 02:05:18

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	24 Sep 2020 12:05:09
User entered 'Day 7'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:56:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-30T23:10:26', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '80874885-a744-45e6-b201-b74b82567312' User entered 'None (0)'	System	01 Oct 2020 03:10:38
	System	01 Oct 2020 03:10:38

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:56:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-30T23:10:27', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '80874885-a744-45e6-b201-b74b82567312' User entered 'None (0)'	System	01 Oct 2020 03:10:38
	System	01 Oct 2020 03:10:38

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:56:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-30T23:10:29', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '80874885-a744-45e6-b201-b74b82567312' User entered 'None (0)'	System	01 Oct 2020 03:10:38
	System	01 Oct 2020 03:10:38

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:56:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-30T23:10:30', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '80874885-a744-45e6-b201-b74b82567312' User entered 'None (0)'	System	01 Oct 2020 03:10:38
	System	01 Oct 2020 03:10:38

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:56:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-30T23:10:31', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '80874885-a744-45e6-b201-b74b82567312' User entered 'None (0)'	System	01 Oct 2020 03:10:38
	System	01 Oct 2020 03:10:38

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:56:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-30T23:10:32', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '80874885-a744-45e6-b201-b74b82567312' User entered 'None (0)'	System	01 Oct 2020 03:10:38
	System	01 Oct 2020 03:10:38

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-30T23:10:34', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '80874885-a744-45e6-b201-b74b82567312' User entered 'No (N)'	System	01 Oct 2020 03:10:38
	System	01 Oct 2020 03:10:38

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:56:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-09-30T23:10:36', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '80874885-a744-45e6-b201-b74b82567312' User entered '30 Sep 2020 23:10'	System	01 Oct 2020 03:10:38
	System	01 Oct 2020 03:10:38

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:56:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 12:05:09

US3822181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:56:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 12:05:09

US3822181

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:36:04

US3822181

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '1 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:36:04

US3822181

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:36:04

US3822181

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:36:04

US3822181

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:36:06

US3822181

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered '1'	System	19 Oct 2020 12:36:06

US3822181

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:36:15

US3822181

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:36:15

US3822181

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:36:15

US3822181

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:36:15

US3822181

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:36:18

US3822181

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered '1'	System	19 Oct 2020 12:36:18

US3822181

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User closed query 'Per GCL Lab Reconciliation: Immunogenicity form is blank, however, there is a Visit 3 Day 57 Immunogenicity sample with a Collection Date of 22OCT2020, per GCL. Please clarify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 06:59:55
Query 'Per GCL Lab Reconciliation: Immunogenicity form is blank, however, there is a Visit 3 Day 57 Immunogenicity sample with a Collection Date of 22OCT2020, per GCL. Please clarify and update as appropriate. ' answered with 'updated' (Site from DM).	Krishna Shah (b) (4) (b) (4)	09 Nov 2020 21:40:07
User opened query 'Per GCL Lab Reconciliation: Immunogenicity form is blank, however, there is a Visit 3 Day 57 Immunogenicity sample with a Collection Date of 22OCT2020, per GCL. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 16:19:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 12:36:27

US3822181

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:36:27

US3822181

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:36:27

US3822181

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:36:27

US3822181

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:36:30

US3822181

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered '1'	System	19 Oct 2020 12:36:30

US3822181

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered 'Yes (Y)'	Krishna Shah (b) (4)	09 Nov 2020 21:38:17

US3822181

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:07

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered '22 Oct 2020'	Krishna Shah (b) (4)	09 Nov 2020 21:38:17

US3822181

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:07

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered 'Clinic (Clinic)'	Krishna Shah (b) (4)	09 Nov 2020 21:38:17

US3822181

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered 'VISIT3'	System	09 Nov 2020 21:38:17

US3822181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered 'Yes (Y)'	Krishna Shah (b) (4)	09 Nov 2020 21:38:59

US3822181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered '22 Oct 2020'	Krishna Shah (b) (4)	09 Nov 2020 21:38:59

US3822181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered '07:25'	Krishna Shah (b) (4)	09 Nov 2020 21:38:59

US3822181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered '22 Oct 2020 07:25'	System	09 Nov 2020 21:38:59

US3822181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered '98.1' F	Krishna Shah (b) (4)	09 Nov 2020 21:38:59

US3822181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered 'Oral (Oral)'	Krishna Shah (b) (4)	09 Nov 2020 21:38:59

US3822181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered empty.	Krishna Shah (b) (4)	09 Nov 2020 21:38:59

US3822181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered '80'	Krishna Shah (b) (4)	09 Nov 2020 21:38:59

US3822181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered 'bpm'	System	09 Nov 2020 21:38:59

US3822181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered '18'	Krishna Shah (b) (4)	09 Nov 2020 21:38:59

US3822181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered 'breaths/min'	System	09 Nov 2020 21:38:59

US3822181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered '120'	Krishna Shah (b) (4)	09 Nov 2020 21:38:59

US3822181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered 'mmHg'	System	09 Nov 2020 21:38:59

US3822181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered '84'	Krishna Shah (b) (4)	09 Nov 2020 21:38:59

US3822181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered 'mmHg'	System	09 Nov 2020 21:38:59

US3822181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25

US3822181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25

US3822181

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:56:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered 'No (N)'	Krishna Shah (b) (4)	09 Nov 2020 21:39:09

US3822181

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:56:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered empty.	Krishna Shah (b) (4)	09 Nov 2020 21:39:09

US3822181

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered 'Yes (Y)'	Krishna Shah (b) (4)	09 Nov 2020 21:39:27

US3822181

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered '22 Oct 2020'	Krishna Shah (b) (4)	09 Nov 2020 21:39:27

US3822181

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered '07:31'	Krishna Shah (b) (4)	09 Nov 2020 21:39:27

US3822181

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered '22 Oct 2020 07:31'	System	09 Nov 2020 21:39:27

US3822181

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:04:13
User entered 'Yes (Y)'	Krishna Shah (b) (4)	09 Nov 2020 21:39:33

US3822181

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered '1'	System	09 Nov 2020 21:39:33

US3822181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered 'Day 64'	System	19 Aug 2020 12:40:08

US3822181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-10-22T18:00:05', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '8a4ccde3-35d4-4d3b-bcf1-1ca199e7ee3b' User entered 'No (N)'	System	22 Oct 2020 22:00:17
	System	22 Oct 2020 22:00:17

US3822181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

Have you been exposed to someone with 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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-10-22T18:00:08', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '8a4ccde3-35d4-4d3b-bcf1-1ca199e7ee3b' User entered 'No (N)'	System	22 Oct 2020 22:00:17
	System	22 Oct 2020 22:00:17

US3822181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-10-22T18:00:10', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '8a4ccde3-35d4-4d3b-bcf1-1ca199e7ee3b' User entered '22 Oct 2020 18:00:10'	System	22 Oct 2020 22:00:17
	System	22 Oct 2020 22:00:17

US3822181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered '19 Oct 2020 00:01'	System	19 Aug 2020 12:40:08

US3822181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered '23 Oct 2020 23:59'	System	19 Aug 2020 12:40:08

US3822181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered 'Day 71'	System	19 Aug 2020 12:40:08

US3822181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-10-28T20:00:20', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '1f570b66-67e9-406a-9003-139bed4ca66a' User entered 'No (N)'	System	29 Oct 2020 00:00:30
	System	29 Oct 2020 00:00:30

US3822181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

Have you been exposed to someone with 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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-10-28T20:00:22', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '1f570b66-67e9-406a-9003-139bed4ca66a' User entered 'No (N)'	System	29 Oct 2020 00:00:30
	System	29 Oct 2020 00:00:30

US3822181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-10-28T20:00:28', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '1f570b66-67e9-406a-9003-139bed4ca66a' User entered '28 Oct 2020 20:00:28'	System	29 Oct 2020 00:00:30
	System	29 Oct 2020 00:00:30

US3822181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered '26 Oct 2020 00:01'	System	19 Aug 2020 12:40:08

US3822181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered '30 Oct 2020 23:59'	System	19 Aug 2020 12:40:08

US3822181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered 'Day 78'	System	19 Aug 2020 12:40:08

US3822181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-11-04T14:33:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '460bf8c0-1d94-49e3-8e9e-5eb90862f876' User entered 'No (N)'	System	04 Nov 2020 19:33:09
	System	04 Nov 2020 19:33:09

US3822181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

Have you been exposed to someone with 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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-11-04T14:33:03', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '460bf8c0-1d94-49e3-8e9e-5eb90862f876'	System	04 Nov 2020 19:33:09
User entered 'No (N)'	System	04 Nov 2020 19:33:09

US3822181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-11-04T14:33:05', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '460bf8c0-1d94-49e3-8e9e-5eb90862f876' User entered '04 Nov 2020 14:33:05'	System	04 Nov 2020 19:33:09
	System	04 Nov 2020 19:33:09

US3822181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered '02 Nov 2020 00:01'	System	19 Aug 2020 12:40:08

US3822181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered '06 Nov 2020 23:59'	System	19 Aug 2020 12:40:08

US3822181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered 'Day 92'	System	19 Aug 2020 12:40:08

US3822181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-11-18T12:01:16', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'b5a42709-d7ef-480c-aa58-82f74ce75d3f' User entered 'No (N)'	System	18 Nov 2020 17:01:29
	System	18 Nov 2020 17:01:29

US3822181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

Have you been exposed to someone with 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 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-11-18T12:01:17', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'b5a42709-d7ef-480c-aa58-82f74ce75d3f' User entered 'No (N)'	System	18 Nov 2020 17:01:29
	System	18 Nov 2020 17:01:29

US3822181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-11-18T12:01:20', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'b5a42709-d7ef-480c-aa58-82f74ce75d3f' User entered '18 Nov 2020 12:01:20'	System	18 Nov 2020 17:01:29
	System	18 Nov 2020 17:01:29

US3822181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered '16 Nov 2020 00:01'	System	19 Aug 2020 12:40:08

US3822181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:18:16
Data entry locked.	System	19 Aug 2020 12:40:08
User entered '20 Nov 2020 23:59'	System	19 Aug 2020 12:40:08

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-11-24T11:19:26', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '0c9f087a-c5c0-4260-b0ec-fa1e00145bad'	System	24 Nov 2020 16:19:46
User entered 'No (N)'	System	24 Nov 2020 16:19:46

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

Have you been exposed to someone with 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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-11-24T11:19:29', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '0c9f087a-c5c0-4260-b0ec-fa1e00145bad'	System	24 Nov 2020 16:19:46
User entered 'Yes (Y)'	System	24 Nov 2020 16:19:46

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Please 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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-11-24T11:19:35', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '0c9f087a-c5c0-4260-b0ec-fa1e00145bad'	System	24 Nov 2020 16:19:46
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Nov 2020 16:19:46

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-11-24T11:19:37', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '0c9f087a-c5c0-4260-b0ec-fa1e00145bad' User entered '24 Nov 2020 11:19:37'	System	24 Nov 2020 16:19:46
	System	24 Nov 2020 16:19:46

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-11-29T12:00:15', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'bd913144-342f-485e-9f58-b59cdaa80481'	System	29 Nov 2020 17:00:26
User entered 'No (N)'	System	29 Nov 2020 17:00:26

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Have you been exposed to someone with 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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-11-29T12:00:20', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'bd913144-342f-485e-9f58-b59cdaa80481'	System	29 Nov 2020 17:00:26
User entered 'No (N)'	System	29 Nov 2020 17:00:26

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-11-29T12:00:22', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'bd913144-342f-485e-9f58-b59cdaa80481'	System	29 Nov 2020 17:00:26
User entered '29 Nov 2020 12:00:22'	System	29 Nov 2020 17:00:26

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-12-06T12:00:30', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '3964229c-2891-4344-9c0b-c364f9dd0f30' User entered 'No (N)'	System	06 Dec 2020 17:00:48
	System	06 Dec 2020 17:00:48

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

Have you been exposed to someone with 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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-12-06T12:00:32', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '3964229c-2891-4344-9c0b-c364f9dd0f30'	System	06 Dec 2020 17:00:48
User entered 'No (N)'	System	06 Dec 2020 17:00:48

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-12-06T12:00:34', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '3964229c-2891-4344-9c0b-c364f9dd0f30' User entered '06 Dec 2020 12:00:34'	System	06 Dec 2020 17:00:48
	System	06 Dec 2020 17:00:48

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-12-14T22:03:09', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '8792550d-2b76-4483-b300-bd1414439ca9'	System	15 Dec 2020 03:03:17
User entered 'No (N)'	System	15 Dec 2020 03:03:17

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

Have you been exposed to someone with 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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-12-14T22:03:10', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '8792550d-2b76-4483-b300-bd1414439ca9'	System	15 Dec 2020 03:03:17
User entered 'No (N)'	System	15 Dec 2020 03:03:17

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-12-14T22:03:12', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '8792550d-2b76-4483-b300-bd1414439ca9' User entered '14 Dec 2020 22:03:12'	System	15 Dec 2020 03:03:17
	System	15 Dec 2020 03:03:17

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-12-20T12:14:13', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '6aaf57ff-6d51-4dbe-8569-cb334351294c'	System	20 Dec 2020 17:14:19
User entered 'No (N)'	System	20 Dec 2020 17:14:19

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

Have you been exposed to someone with 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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-12-20T12:14:14', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '6aaf57ff-6d51-4dbe-8569-cb334351294c' User entered 'No (N)'	System	20 Dec 2020 17:14:19

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-12-20T12:14:16', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '6aaf57ff-6d51-4dbe-8569-cb334351294c' User entered '20 Dec 2020 12:14:16'	System	20 Dec 2020 17:14:19
	System	20 Dec 2020 17:14:19

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-12-25T07:49:02', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '5442b83b-5b57-44bf-8142-bbbfb06a8c39' User entered 'No (N)'	System	25 Dec 2020 12:49:28
	System	25 Dec 2020 12:49:28

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

Have you been exposed to someone with 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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-12-25T07:49:06', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '5442b83b-5b57-44bf-8142-bbbfb06a8c39'	System	25 Dec 2020 12:49:28
User entered 'Yes (Y)'	System	25 Dec 2020 12:49:28

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Please 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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-12-25T07:49:16', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '5442b83b-5b57-44bf-8142-bbbfb06a8c39'	System	25 Dec 2020 12:49:28
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Dec 2020 12:49:28

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2020-12-25T07:49:18', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '5442b83b-5b57-44bf-8142-bbbfb06a8c39' User entered '25 Dec 2020 07:49:18'	System	25 Dec 2020 12:49:28
	System	25 Dec 2020 12:49:28

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-01-01T09:50:42', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '5c2266e0-3d61-4d9c-b962-36f30c83393a' User entered 'No (N)'	System	01 Jan 2021 14:50:48
	System	01 Jan 2021 14:50:48

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Have you been exposed to someone with 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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-01-01T09:50:44', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '5c2266e0-3d61-4d9c-b962-36f30c83393a' User entered 'No (N)'	System	01 Jan 2021 14:50:48

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-01-01T09:50:46', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '5c2266e0-3d61-4d9c-b962-36f30c83393a' User entered '01 Jan 2021 09:50:46'	System	01 Jan 2021 14:50:48
	System	01 Jan 2021 14:50:48

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-01-09T08:23:08', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '7ce11e52-3d6d-4f70-80b2-ec3ed57ced8a' User entered 'No (N)'	System	09 Jan 2021 13:23:13

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Have you been exposed to someone with 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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-01-09T08:23:09', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '7ce11e52-3d6d-4f70-80b2-ec3ed57ced8a' User entered 'No (N)'	System	09 Jan 2021 13:23:13

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-01-09T08:23:11', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '7ce11e52-3d6d-4f70-80b2-ec3ed57ced8a' User entered '09 Jan 2021 08:23:11'	System	09 Jan 2021 13:23:13
	System	09 Jan 2021 13:23:13

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-01-17T13:13:40', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '47bdc12-5b97-4eb7-b895-c943d2c1fedb' User entered 'No (N)'	System	17 Jan 2021 17:13:46
	System	17 Jan 2021 17:13:46

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Have you been exposed to someone with 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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-01-17T13:13:41', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '47bdc12-5b97-4eb7-b895-c943d2c1fedb' User entered 'No (N)'	System	17 Jan 2021 17:13:46

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-01-17T13:13:43', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '47bdc12-5b97-4eb7-b895-c943d2c1fedb' User entered '17 Jan 2021 13:13:43'	System	17 Jan 2021 17:13:46
	System	17 Jan 2021 17:13:46

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-01-22T06:00:52', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '23261ad7-941f-4e4f-ba40-004aec195217'	System	22 Jan 2021 11:00:58
User entered 'No (N)'	System	22 Jan 2021 11:00:58

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

Have you been exposed to someone with 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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-01-22T06:00:53', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '23261ad7-941f-4e4f-ba40-004aec195217'	System	22 Jan 2021 11:00:58
User entered 'No (N)'	System	22 Jan 2021 11:00:58

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-01-22T06:00:56', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '23261ad7-941f-4e4f-ba40-004aec195217'	System	22 Jan 2021 11:00:58
User entered '22 Jan 2021 06:00:56'	System	22 Jan 2021 11:00:58

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-01-30T22:29:45', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '1233e787-bc8a-4020-bec0-6e447a261e46' User entered 'No (N)'	System	31 Jan 2021 03:40:17

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Have you been exposed to someone with 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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-01-30T22:29:46', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '1233e787-bc8a-4020-bec0-6e447a261e46'	System	31 Jan 2021 03:40:17
User entered 'No (N)'	System	31 Jan 2021 03:40:17

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-01-30T22:29:48', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '1233e787-bc8a-4020-bec0-6e447a261e46' User entered '30 Jan 2021 22:29:48'	System	31 Jan 2021 03:40:17
	System	31 Jan 2021 03:40:17

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-02-07T12:03:40', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '9d4c9a20-ae11-4f57-a11b-22db762f0e70' User entered 'No (N)'	System	07 Feb 2021 17:06:51

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Have you been exposed to someone with 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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-02-07T12:03:42', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '9d4c9a20-ae11-4f57-a11b-22db762f0e70'	System	07 Feb 2021 17:06:51
User entered 'No (N)'	System	07 Feb 2021 17:06:51

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-02-07T12:03:44', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '9d4c9a20-ae11-4f57-a11b-22db762f0e70' User entered '07 Feb 2021 12:03:44'	System	07 Feb 2021 17:06:51
	System	07 Feb 2021 17:06:51

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-02-14T12:03:56', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '7041d062-f6ea-4faf-ac2e-4641113dab27'	System	14 Feb 2021 17:09:31
User entered 'No (N)'	System	14 Feb 2021 17:09:31

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

Have you been exposed to someone with 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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-02-14T12:03:57', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '7041d062-f6ea-4faf-ac2e-4641113dab27'	System	14 Feb 2021 17:09:31
User entered 'No (N)'	System	14 Feb 2021 17:09:31

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-02-14T12:03:59', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '7041d062-f6ea-4faf-ac2e-4641113dab27'	System	14 Feb 2021 17:09:31
User entered '14 Feb 2021 12:03:59'	System	14 Feb 2021 17:09:31

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-02-20T16:21:14', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'e9b47e56-ca7b-4760-a8ae-40cddf4fe6cf' User entered 'No (N)'	System	20 Feb 2021 21:21:26

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

Have you been exposed to someone with 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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-02-20T16:21:18', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'e9b47e56-ca7b-4760-a8ae-40cddf4fe6cf' User entered 'No (N)'	System	20 Feb 2021 21:21:26

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-02-20T16:21:22', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'e9b47e56-ca7b-4760-a8ae-40cddf4fe6cf' User entered '20 Feb 2021 16:21:22'	System	20 Feb 2021 21:21:26
	System	20 Feb 2021 21:21:26

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-02-27T07:36:23-05:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '814ccd34-08ec-43bb-9cf3-20f8fef1a91a' User entered 'No (N)'	System	27 Feb 2021 12:36:29
	System	27 Feb 2021 12:36:29

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

Have you been exposed to someone with 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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-02-27T07:36:24-05:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '814ccd34-08ec-43bb-9cf3-20f8fef1a91a' User entered 'No (N)'	System	27 Feb 2021 12:36:29

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-02-27T07:36:26-05:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '814ccd34-08ec-43bb-9cf3-20f8fef1a91a' User entered '27 Feb 2021 12:36:26'	System	27 Feb 2021 12:36:29
	System	27 Feb 2021 12:36:29

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-03-05T07:38:32-05:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'd486453e-5fcc-4632-90d0-f0f20b9effca'	System	05 Mar 2021 12:38:39
User entered 'No (N)'	System	05 Mar 2021 12:38:39

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

Have you been exposed to someone with 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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-03-05T07:38:34-05:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'd486453e-5fcc-4632-90d0-f0f20b9effca'	System	05 Mar 2021 12:38:39
User entered 'No (N)'	System	05 Mar 2021 12:38:39

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-03-05T07:38:37-05:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'd486453e-5fcc-4632-90d0-f0f20b9effca' User entered '05 Mar 2021 07:38:37'	System	05 Mar 2021 12:38:39
	System	05 Mar 2021 12:38:39

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-03-14T12:30:24-04:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '56779712-08fd-41d7-a115-e664c7e05ee9'	System	14 Mar 2021 16:30:29
User entered 'No (N)'	System	14 Mar 2021 16:30:29

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

Have you been exposed to someone with 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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-03-14T12:30:25-04:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '56779712-08fd-41d7-a115-e664c7e05ee9'	System	14 Mar 2021 16:30:29
User entered 'No (N)'	System	14 Mar 2021 16:30:29

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-03-14T12:30:26-04:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '56779712-08fd-41d7-a115-e664c7e05ee9' User entered '14 Mar 2021 12:30:26'	System	14 Mar 2021 16:30:29
	System	14 Mar 2021 16:30:29

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-03-21T12:28:30-04:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'faa64c7a-4a55-4d5a-ac25-c061bb207c50'	System	21 Mar 2021 16:28:37
User entered 'No (N)'	System	21 Mar 2021 16:28:37

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

Have you been exposed to someone with 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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-03-21T12:28:31-04:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'faa64c7a-4a55-4d5a-ac25-c061bb207c50'	System	21 Mar 2021 16:28:37
User entered 'No (N)'	System	21 Mar 2021 16:28:37

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-03-21T12:28:33-04:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'faa64c7a-4a55-4d5a-ac25-c061bb207c50' User entered '21 Mar 2021 12:28:33'	System	21 Mar 2021 16:28:37
	System	21 Mar 2021 16:28:37

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-03-28T12:21:53-04:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'd23d96d8-5d0c-4f9c-9140-479b384afcfb'	System	28 Mar 2021 16:22:00
User entered 'No (N)'	System	28 Mar 2021 16:22:00

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

Have you been exposed to someone with 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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-03-28T12:21:55-04:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'd23d96d8-5d0c-4f9c-9140-479b384afcfb'	System	28 Mar 2021 16:22:00
User entered 'No (N)'	System	28 Mar 2021 16:22:00

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-03-28T12:21:56-04:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'd23d96d8-5d0c-4f9c-9140-479b384afcfb' User entered '28 Mar 2021 12:21:56'	System	28 Mar 2021 16:22:00
	System	28 Mar 2021 16:22:00

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-04-04T12:14:38-04:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'd5f3da6b-8cbf-4f83-8090-5ec11f575303'	System	04 Apr 2021 16:14:42
User entered 'No (N)'	System	04 Apr 2021 16:14:42

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

Have you been exposed to someone with 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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-04-04T12:14:39-04:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'd5f3da6b-8cbf-4f83-8090-5ec11f575303'	System	04 Apr 2021 16:14:42
User entered 'No (N)'	System	04 Apr 2021 16:14:42

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-04-04T12:14:41-04:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'd5f3da6b-8cbf-4f83-8090-5ec11f575303'	System	04 Apr 2021 16:14:42
User entered '04 Apr 2021 12:14:41'	System	04 Apr 2021 16:14:42

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-04-11T12:00:31-05:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '24fc1a95-1680-46c6-9d04-e316f2cffba2' User entered 'No (N)'	System	11 Apr 2021 17:00:50
	System	11 Apr 2021 17:00:50

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

Have you been exposed to someone with 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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-04-11T12:00:33-05:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '24fc1a95-1680-46c6-9d04-e316f2cffba2'	System	11 Apr 2021 17:00:50
User entered 'No (N)'	System	11 Apr 2021 17:00:50

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-04-11T12:00:35-05:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '24fc1a95-1680-46c6-9d04-e316f2cffba2'	System	11 Apr 2021 17:00:50
User entered '11 Apr 2021 12:00:35'	System	11 Apr 2021 17:00:50

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-04-18T12:10:07-04:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'd414c9a2-8bd3-4427-aad1-d0a143af83d8'	System	18 Apr 2021 16:10:13
User entered 'No (N)'	System	18 Apr 2021 16:10:13

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

Have you been exposed to someone with 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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-04-18T12:10:08-04:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'd414c9a2-8bd3-4427-aad1-d0a143af83d8'	System	18 Apr 2021 16:10:13
User entered 'No (N)'	System	18 Apr 2021 16:10:13

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-04-18T12:10:09-04:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'd414c9a2-8bd3-4427-aad1-d0a143af83d8'	System	18 Apr 2021 16:10:13
User entered '18 Apr 2021 12:10:09'	System	18 Apr 2021 16:10:13

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-04-25T12:40:44-04:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'f483c839-2335-4fa6-a28d-1b474bd52be9' User entered 'No (N)'	System	25 Apr 2021 16:40:55
	System	25 Apr 2021 16:40:55

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

Have you been exposed to someone with 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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-04-25T12:40:46-04:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'f483c839-2335-4fa6-a28d-1b474bd52be9'	System	25 Apr 2021 16:40:55
User entered 'No (N)'	System	25 Apr 2021 16:40:55

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-04-25T12:40:51-04:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'f483c839-2335-4fa6-a28d-1b474bd52be9' User entered '25 Apr 2021 12:40:51'	System	25 Apr 2021 16:40:55
	System	25 Apr 2021 16:40:55

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-05-02T12:31:12-04:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'f774d4d8-4b6d-4097-91b2-3aea240fa094'	System	02 May 2021 16:31:23
User entered 'No (N)'	System	02 May 2021 16:31:23

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Have you been exposed to someone with 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 (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-05-02T12:31:16-04:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'f774d4d8-4b6d-4097-91b2-3aea240fa094'	System	02 May 2021 16:31:23
User entered 'No (N)'	System	02 May 2021 16:31:23

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-05-02T12:31:18-04:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: 'f774d4d8-4b6d-4097-91b2-3aea240fa094'	System	02 May 2021 16:31:23
User entered '02 May 2021 12:31:18'	System	02 May 2021 16:31:23

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 22:43:03

US3822181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:43:03
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 22:43:03

US3822181

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:56:07

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)	25 Apr 2021 18:34:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-03-05T07:38:25-05:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '054ff24c-3b08-47e2-a920-275d6956d04b'	System	05 Mar 2021 12:38:31
User entered 'No (N)'	System	05 Mar 2021 12:38:31

US3822181

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:56:07

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:34:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67F001C2-61F2-4C5D-8736-C803FAB4F05A)', Time: '2021-03-05T07:38:28-05:00', User OID: 'PatientReportedOutcome (US3822181)', ODM File OID: '054ff24c-3b08-47e2-a920-275d6956d04b' User entered '05 Mar 2021 07:38:28'	System	05 Mar 2021 12:38:31
	System	05 Mar 2021 12:38:31

US3822181

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:14:22
User entered 'Yes (Y)'	Krishna Shah (b) (4)	03 Dec 2020 14:25:33

US3822181

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:14:22
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:53:45
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Visit date is correct. Visit occurred 3 days (early) out of window. Deviation noted. ' (Site from System).	Krishna Shah (b) (4) (b) (4)	03 Dec 2020 14:31:08
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	03 Dec 2020 14:25:33
User entered '12 Nov 2020'	Krishna Shah (b) (4) (b) (4)	03 Dec 2020 14:25:33

US3822181

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:14:22
User entered 'Contact Made (CONTACT MADE)'	Krishna Shah (b) (4)	03 Dec 2020 14:25:33

US3822181

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:14:22
User entered empty.	Krishna Shah (b) (4)	03 Dec 2020 14:25:33

US3822181

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:14:22
User entered 'Yes (Y)'	Krishna Shah (b) (4)	03 Dec 2020 14:25:39

US3822181

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:28:25
User entered '1'	System	03 Dec 2020 14:25:39

US3822181

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:40:34
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 07JAN2020 for the Participant Decision Visit, however, there is no data recorded for the Participant Decision Visit. Please clarify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:48:00
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 07JAN2020 for the Participant Decision Visit, however, there is no data recorded for the Participant Decision Visit. Please clarify and update as appropriate.' answered with 'All data has been entered ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 20:58:35
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 07JAN2020 for the Participant Decision Visit, however, there is no data recorded for the Participant Decision Visit. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 20:24:23
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	12 Jan 2021 00:09:11

US3822181

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:40:34
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered '17 Dec 2020'	Kelly Woodell (b) (4)	12 Jan 2021 00:09:11

US3822181

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:40:34
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'Contact Made (CONTACT MADE)'	Kelly Woodell (b) (4)	12 Jan 2021 00:09:11

US3822181

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:40:34
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered empty.	Kelly Woodell (b) (4)	12 Jan 2021 00:09:11

US3822181

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:40:34
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	12 Jan 2021 00:09:14

US3822181

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:40:34
User entered '1'	System	12 Jan 2021 00:09:14

US3822181

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:40:34
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	27 Jan 2021 15:56:50

US3822181

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:40:34
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered '19 Jan 2021'	Kelly Woodell (b) (4)	27 Jan 2021 15:56:50

US3822181

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:40:34
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'Contact Made (CONTACT MADE)'	Kelly Woodell (b) (4)	27 Jan 2021 15:56:50

US3822181

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:40:34
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered empty.	Kelly Woodell (b) (4)	27 Jan 2021 15:56:50

US3822181

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:40:34
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	27 Jan 2021 15:56:53

US3822181

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:40:34
User entered '1'	System	27 Jan 2021 15:56:53

US3822181

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:40:34
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:12:38

US3822181

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:40:34
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 07:27:28
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Safety call is 5 days out of window, deviation noted' (Site from System).	(b) (4), (b) (6)	12 Feb 2021 17:13:23
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	12 Feb 2021 17:12:38
User entered '11 Feb 2021'	(b) (4), (b) (6)	12 Feb 2021 17:12:38

US3822181

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:40:34
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:12:38

US3822181

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:40:34
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:12:38

US3822181

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:40:34
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:13:27

US3822181

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:40:34
User entered '1'	System	12 Feb 2021 17:13:27

US3822181

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 11:30:48

US3822181

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:07

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 11:30:48

US3822181

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:07

[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 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 11:30:48

US3822181

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User entered 'VISIT4'	System	25 Mar 2021 11:30:48

US3822181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:58:02

US3822181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:58:02

US3822181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:58:02

US3822181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User entered empty.	System	01 Apr 2021 15:58:02

US3822181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:58:02

US3822181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:58:02

US3822181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:58:02

US3822181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:58:02

US3822181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User entered empty.	System	01 Apr 2021 15:58:02

US3822181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:58:02

US3822181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User entered empty.	System	01 Apr 2021 15:58:02

US3822181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:58:02

US3822181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User entered empty.	System	01 Apr 2021 15:58:02

US3822181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:58:02

US3822181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User entered empty.	System	01 Apr 2021 15:58:02

US3822181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38

US3822181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:07

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38

US3822181

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:56:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 11:30:55

US3822181

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:56:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 11:30:55

US3822181

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 11:31:08

US3822181

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 11:31:08

US3822181

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered '07:15'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 11:31:08

US3822181

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User entered '25 Mar 2021 07:15'	System	25 Mar 2021 11:31:08

US3822181

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 11:31:13

US3822181

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:32:38
User entered '1'	System	25 Mar 2021 11:31:13

US3822181

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:26:21
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:45:26

US3822181

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:07

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:26:21
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered '07 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:45:26

US3822181

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:07

[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 23:26:21
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:45:26

US3822181

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:26:21
User entered 'UNBLND_DECIDE'	System	21 Jan 2021 15:45:26

US3822181

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:56:07

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:26:21
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered '07 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:45:43

US3822181

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:56:07

[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 23:26:21
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:04:51
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:31:34
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:02:38

US3822181

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:56:07

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:26:21
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:45:43

US3822181

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:56:07

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:26:21
User closed query 'Per CDM: Per Sponsor review: 'Under what version of the Protocol was the participant unblinded?' is blank - 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. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 03:42:05
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:04:51
Query 'Per CDM: Per Sponsor review: 'Under what version of the Protocol was the participant unblinded?' is blank - 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. Thank you. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 12:33:14
User entered 'Amendment 5 (Amendment 5)'	(b) (4), (b) (6)	09 Apr 2021 12:31:34
User opened query 'Per CDM: Per Sponsor review: 'Under what version of the Protocol was the participant unblinded?' is blank - 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. Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 12:58:58
Query 'US3822181Per CDM: Per Sponsor review: 'Under what version of the Protocol was the participant unblinded?' is blank - 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. Thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 12:58:43
User opened query 'US3822181Per CDM: Per Sponsor review: 'Under what version of the Protocol was the participant unblinded?' is blank - 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. Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 12:58:02
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:02:38

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EAB) (1725)

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:56:07

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:26:21
User signature succeeded.	Christina Kennelly (b) (4)	23 Apr 2021 14:40:00
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 10:41:32
User closed query 'Per CDM RQ: Response noted. However, this field is the date of unblinding in IRT. Please reconcile. Thank you' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 10:41:31
Query 'Per CDM RQ: Response noted. However, this field is the date of unblinding in IRT. Please reconcile. Thank you' answered with 'updated per IRT' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 16:22:29
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered with 'Patient unblinded in IRT prior to coming into clinic to actually be unblinded' (Site from System).	(b) (4), (b) (6)	16 Apr 2021 16:22:24
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	16 Apr 2021 16:22:19
Signature has been broken.	(b) (4), (b) (6)	16 Apr 2021 16:22:19
User entered '06 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 16:22:19
User opened query 'Per CDM RQ: Response noted. However, this field is the date of unblinding in IRT. Please reconcile. Thank you' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 14:59:55
User closed query 'Per CDM : Per IRT : subject was unblinded on 06JAN2021. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 14:59:55
Query 'Per CDM : Per IRT : subject was unblinded on 06JAN2021. Please review and reconcile.' answered with 'Patient unblinded in IRT done 06JAN2021 but patient actually brought in to be unblinded in clinic on 07JAN2021.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 12:33:44
User opened query 'Per CDM : Per IRT : subject was unblinded on 06JAN2021. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 14:29:59

US3822181

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:56:07

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered '07 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:45:43

US3822181

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:56:07

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:26:21
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:45:43

US3822181

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:56:07

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:26:21
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:45:43

US3822181

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:56:07

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:26:21
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:45:43

US3822181

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:56:07

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:26:21
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:45:43

US3822181

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:56:07

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:26:21
User entered empty.	System	21 Jan 2021 15:45:43

US3822181

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:56:07

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:26:21
User entered empty.	System	21 Jan 2021 15:45:43

US3822181

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:26:21
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:45:53

US3822181

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:07

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:26:21
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered '07 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:45:53

US3822181

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:07

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:26:21
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered '16:26'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:45:53

US3822181

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:26:21
User entered '07 Jan 2021 16:26'	System	21 Jan 2021 15:45:53

US3822181

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:56:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:26:21
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:45:07

US3822181

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:56:07

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:26:21
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered '07 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:45:07

US3822181

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:56:07

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:26:21
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered '16:48'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:45:07

US3822181

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:56:07

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:26:21
User entered '07 Jan 2021 16:48'	System	21 Jan 2021 15:45:07

US3822181

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:56:07

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:13:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 14:24:23
User signature succeeded.	Christina Kennelly (b) (4)	19 Mar 2021 20:11:00
User closed query 'Per CDM: "Did the participant experience any adverse events?" is marked as No; however, data is recorded in the Adverse Events page. Please review and update accordingly. Thank you.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 10:05:14
' (Site from DM).		
Query 'Per CDM: "Did the participant experience any adverse events?" is marked as No; however, data is recorded in the Adverse Events page. Please review and update accordingly. Thank you.	(b) (4), (b) (6)	15 Mar 2021 14:42:23
' answered with 'updated' (Site from DM).		
Signature has been broken.	(b) (4), (b) (6)	15 Mar 2021 14:42:17
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 14:42:17
User opened query 'Per CDM: "Did the participant experience any adverse events?" is marked as No; however, data is recorded in the Adverse Events page. Please review and update accordingly. Thank you.	(b) (4), (b) (6)	15 Mar 2021 13:39:29
' (Site from DM).		
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:54:07
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Kelly Woodell (b) (4)	08 Feb 2021 15:50:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 12:37:06

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered	(b) (4)	
'USA-US126-2021-mRNA-1273-P301000006'	(b) (4), (b) (6)	24 Mar 2021 17:40:39

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\\23.0.	Coder Import (b) (4)	04 Mar 2021 13:32:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Mar 2021 13:32:00
Data point term sent to Coder	System	04 Mar 2021 13:30:58
User entered 'Appendicitis'	(b) (4), (b) (6)	04 Mar 2021 13:30:42

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 13:30:42

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 13:30:42

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 13:30:42

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered '3 Mar 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 13:30:42

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
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)	04 Mar 2021 13:31:05
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 13:31:05
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	04 Mar 2021 13:30:42
User entered '00:00'	(b) (4), (b) (6)	04 Mar 2021 13:30:42

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Mar 2021 13:31:05
User entered '3 Mar 2021 00:00'	System	04 Mar 2021 13:30:42

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 13:30:42

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered '4 Mar 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:06:15
User entered '3 Mar 2021'	(b) (4), (b) (6)	04 Mar 2021 13:30:42

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4)	04 Mar 2021 13:31:05
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 13:31:05
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	04 Mar 2021 13:30:42
User entered '22:00'	(b) (4), (b) (6)	04 Mar 2021 13:30:42

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Mar 2021 13:31:05
User entered '3 Mar 2021 22:00'	System	04 Mar 2021 13:30:42

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 13:30:42

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	(b) (4)	04 Mar 2021 13:31:22
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 13:31:22
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	04 Mar 2021 13:30:42
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 13:30:42

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 13:30:42

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 13:30:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered '1'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 13:30:42

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered '3 Mar 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 13:30:42

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered '4 Mar 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 13:30:42

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 13:30:42

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 13:30:42

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 13:30:42

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 13:30:42

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 13:30:42

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 13:30:42

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 13:30:42

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 13:30:42

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 13:30:42

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 13:30:42

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered '1'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 13:30:42

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 13:30:42

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 13:30:42

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 23:28:27
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 23:28:25
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' answered with 'CT scan showed appendicitis. Will send over lab and diagnostic results to Safety_Moderna@iqvia.com' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 14:09:22
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' answered with 'Covid-19 nasal swab completed on 03MAR2021 prior to surgery and it was negative.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 13:13:15
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 19:38:39

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 13:31:22
User entered '0'	System	04 Mar 2021 13:30:42

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 13:30:42

US3822181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:07

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Mar 2021 13:30:42

US3822181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:07

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Clostridia infections, PT: Clostridium difficile infection, LLT: Clostridium difficile infection - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 15:11:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 15:11:38
Data point term sent to Coder	System	23 Mar 2021 15:10:15
User entered 'C diff'	(b) (4), (b) (6)	23 Mar 2021 15:09:24

US3822181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:09:24

US3822181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:09:24

US3822181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:09:24

US3822181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered '9 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:09:24

US3822181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:07

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:09:24

US3822181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 15:09:24

US3822181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:09:24

US3822181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:09:24

US3822181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:07

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:09:24

US3822181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 15:09:24

US3822181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:07

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:09:24

US3822181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:09:24

US3822181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:07

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:09:24

US3822181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:07

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:09:24

US3822181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:09:24

US3822181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:09:24

US3822181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:09:24

US3822181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:09:24

US3822181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:09:24

US3822181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:09:24

US3822181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:09:24

US3822181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:07

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:09:24

US3822181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:09:24

US3822181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:09:24

US3822181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:09:24

US3822181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:07

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:09:24

US3822181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered '1'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:09:24

US3822181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:09:24

US3822181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:07

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:09:24

US3822181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:09:24

US3822181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:07

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:05:11
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:30
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:09:24

US3822181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	23 Mar 2021 15:09:24

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:56:07

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 15:09:24

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:56:07

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:13:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User closed query 'Per DM CLR: Diary Dose 1 Day 2, indicates that Medication was taken for HEADACHE on 25SEP2020, 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) (4), (b) (6)	03 Feb 2021 09:33:02
Query 'Per DM CLR: Diary Dose 1 Day 2, indicates that Medication was taken for HEADACHE on 25SEP2020, 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 'Per patient day 36 phone call sheet in CRIO, patient did NOT take medication for headache. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 18:59:10
User opened query 'Per DM CLR: Diary Dose 1 Day 2, indicates that Medication was taken for HEADACHE on 25SEP2020, 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)	31 Jan 2021 10:13:22
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	15 Sep 2020 23:52:09

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:56:07

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: VASOPROTECTIVES, ATC: AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL FISSURES FOR TOPICAL USE, ATC: OTHER AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL FISSURES FOR TOPICAL USE, PRODUCT: OTHER AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL FISSURES FOR TOPICAL USE - version WHODrug-Global-B3\\202003.	(b) (4) Coders Import (b) (4) (b) (4)	24 Nov 2020 17:19:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coders Import (b) (4) (b) (4)	24 Nov 2020 17:19:55
Data point term sent to Coder	System	09 Nov 2020 21:43:24
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	09 Nov 2020 21:43:13
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'patient stated only cream used. ' (Site from System).	Krishna Shah (b) (4) (b) (4)	09 Nov 2020 21:43:13
User entered 'PREPARATION H cream' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	09 Nov 2020 21:43:01
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coders Import (b) (4) (b) (4)	17 Sep 2020 07:55:48
Data point term sent to Coder	System	15 Sep 2020 23:53:26
User entered 'Preparation H'	Kelly Woodell (b) (4) (b) (4)	15 Sep 2020 23:52:57

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:56:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
	(b) (4)	
User entered 'No (N)'	Kelly Woodell (b) (4)	15 Sep 2020 23:52:57
	(b) (4)	

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:56:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'Hemorrhoids'	(b) (4) Kelly Woodell (b) (4)	15 Sep 2020 23:52:57

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:56:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
	(b) (4)	
User entered '1'	Kelly Woodell (b) (4)	15 Sep 2020 23:52:57
	(b) (4)	

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:56:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
	(b) (4)	
User entered 'Other (OTHER)'	Kelly Woodell (b) (4)	15 Sep 2020 23:52:57
	(b) (4)	

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:56:07

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'application'	(b) (4) Kelly Woodell (b) (4) (b) (4)	15 Sep 2020 23:52:57

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:56:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'as needed (PRN)'	(b) (4) Kelly Woodell (b) (4) (b) (4)	15 Sep 2020 23:52:57

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:56:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered empty.	(b) (4) Kelly Woodell (b) (4) (b) (4)	15 Sep 2020 23:52:57

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:56:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'Topical (TOPICAL)'	(b) (4) Kelly Woodell (b) (4) (b) (4)	15 Sep 2020 23:52:57

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:56:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered empty.	(b) (4) Kelly Woodell (b) (4)	15 Sep 2020 23:52:57

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:56:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
	(b) (4)	
User entered 'un UNK 2020'	Kelly Woodell (b) (4)	15 Sep 2020 23:52:57
	(b) (4)	

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:56:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
	(b) (4)	
User entered '0'	Kelly Woodell (b) (4)	15 Sep 2020 23:52:57
	(b) (4)	

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:56:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'Yes (Y)'	(b) (4) Kelly Woodell (b) (4) (b) (4)	15 Sep 2020 23:52:57

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:56:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
	(b) (4)	
User entered empty.	Kelly Woodell (b) (4)	15 Sep 2020 23:52:57
	(b) (4)	

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:56:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'No (N)'	(b) (4) Kelly Woodell (b) (4) (b) (4)	15 Sep 2020 23:52:57

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:56:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 23:52:57

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:56:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 23:52:57

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:56:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 23:52:57

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:54
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Sep 2020 23:55:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Sep 2020 23:55:53
Data point term sent to Coder	System	15 Sep 2020 23:54:28
User entered 'Influenza vaccine'	Kelly Woodell (b) (4)	15 Sep 2020 23:54:08

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:54
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	15 Sep 2020 23:54:08

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:54
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'Influenza'	Kelly Woodell (b) (4)	15 Sep 2020 23:54:08

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:54
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered '.5'	Kelly Woodell (b) (4)	15 Sep 2020 23:54:08

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:54
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'mL (mL)'	Kelly Woodell (b) (4)	15 Sep 2020 23:54:08

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:54
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered empty.	Kelly Woodell (b) (4)	15 Sep 2020 23:54:08

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:54
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'once (ONCE)'	Kelly Woodell (b) (4)	15 Sep 2020 23:54:08

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:54
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered empty.	Kelly Woodell (b) (4)	15 Sep 2020 23:54:08

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:54
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'Intramuscular (INTRAMUSCULAR)'	Kelly Woodell (b) (4)	15 Sep 2020 23:54:08

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:54
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered empty.	Kelly Woodell (b) (4)	15 Sep 2020 23:54:08

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:54
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'un UNK 2019'	Kelly Woodell (b) (4)	15 Sep 2020 23:54:08

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:54
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered '0'	Kelly Woodell (b) (4)	15 Sep 2020 23:54:08

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:54
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'No (N)'	Kelly Woodell (b) (4)	15 Sep 2020 23:54:08

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:54
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'un UNK 2019'	Kelly Woodell (b) (4)	15 Sep 2020 23:54:08

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:54
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'No (N)'	Kelly Woodell (b) (4)	15 Sep 2020 23:54:08

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:54
User entered empty.	System	15 Sep 2020 23:54:08

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:54
User entered empty.	System	15 Sep 2020 23:54:08

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:54
User entered empty.	System	15 Sep 2020 23:54:08

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:13
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
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: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Oct 2020 12:40:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 12:40:39
Data point term sent to Coder	System	19 Oct 2020 12:39:35
User entered 'Aleve'	(b) (4), (b) (6)	19 Oct 2020 12:38:51

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:13
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:38:51

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:07

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:13
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
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 INJECTION SITE PAIN 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 INJECTION SITE PAIN did not meet the AE reporting criteria' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 11:21:04
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN 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 INJECTION SITE PAIN did not meet the AE reporting criteria' answered with 'Medication for solicited AE that does not meet AE reporting criteria. ' (Site from DM).	Krishna Shah (b) (4) (b) (4)	09 Nov 2020 21:36:00

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:07

[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 INJECTION SITE PAIN 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 INJECTION SITE PAIN did not meet the AE reporting criteria' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 10:31:43
User entered 'Injection site pain'	(b) (4), (b) (6)	19 Oct 2020 12:38:51

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:13
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User closed query 'Per DM CLR: Please review the dose recorded as this is not the usual dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 11:21:37
Query 'Per DM CLR: Please review the dose recorded as this is not the usual dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'updated' (Site from DM).	Krishna Shah (b) (4) (b) (4)	09 Nov 2020 21:36:40
User entered '220' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	09 Nov 2020 21:36:33
User opened query 'Per DM CLR: Please review the dose recorded as this is not the usual dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 10:31:27
User entered '200'	(b) (4), (b) (6)	19 Oct 2020 12:38:51

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:13
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:38:51

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:07

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:13
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:38:51

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:13
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:38:51

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:13
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:38:51

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:13
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:38:51

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:13
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:38:51

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:13
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered '25 Sep 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:38:51

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:13
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:38:51

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:13
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:38:51

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:13
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered '25 Sep 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:38:51

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:13
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:38:51

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:13
User entered '1'	System	19 Oct 2020 12:38:51

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:13
User entered '1'	System	19 Oct 2020 12:38:51

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:13
User entered '804 (804)'	System	19 Oct 2020 12:38:51

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Oct 2020 12:40:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 12:40:39
Data point term sent to Coder	System	19 Oct 2020 12:39:35
User entered 'Mucinex'	(b) (4), (b) (6)	19 Oct 2020 12:39:31

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:39:31

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
Query 'Per DM CLR : Please note 'Was this medication taken for solicited event?' = Yes, however, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review if this is considered a solicited local or systemic adverse reaction and if not, please update response as appropriate. Otherwise, please provide comment.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 10:33:48
' canceled (Site from DM).		
User opened query 'Per DM CLR : Please note 'Was this medication taken for solicited event?' = Yes, however, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review if this is considered a solicited local or systemic adverse reaction and if not, please update response as appropriate. Otherwise, please provide comment.	(b) (4), (b) (6)	05 Nov 2020 10:33:39
' (Site from DM).		
User entered 'Cough'	(b) (4), (b) (6)	19 Oct 2020 12:39:31

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered '600'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:39:31

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:39:31

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:39:31

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:39:31

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:39:31

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:39:31

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:39:31

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:39:31

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:39:31

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:39:31

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:39:31

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User closed query 'Per DM CLR : Please note 'Was this medication taken for solicited event?' = Yes, however, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review if this is considered a solicited local or systemic adverse reaction and if not, please update response as appropriate. Otherwise, please provide comment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 09:37:52
Query 'Per DM CLR : Please note 'Was this medication taken for solicited event?' = Yes, however, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review if this is considered a solicited local or systemic adverse reaction and if not, please update response as appropriate. Otherwise, please provide comment. ' answered with 'Medication taken for solicited AE that does not meet AE reporting criteria. ' (Site from DM).	Krishna Shah (b) (4) (b) (4)	09 Nov 2020 21:45:26

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR : Please note 'Was this medication taken for solicited event?' = Yes, however, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review if this is considered a solicited local or systemic adverse reaction and if not, please update response as appropriate. Otherwise, please provide comment. ' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	05 Nov 2020 10:33:53 19 Oct 2020 12:39:31

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Oct 2020 12:39:31

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 12:39:31

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 12:39:31

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: INTESTINAL ANTIINFECTIVES, ATC: ANTIBIOTICS, PRODUCT: VANCOMYCIN HYDROCHLORIDE, PRODUCTSYNONYM: VANCOMYCIN HCL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Mar 2021 09:06:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 09:06:29
Data point term sent to Coder	System	23 Mar 2021 15:05:01
User entered 'Vancomycin HCl'	(b) (4), (b) (6) (b) (4) (b) (4)	23 Mar 2021 15:04:50

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:04:50

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'C Diff'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:04:50

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered '125'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:04:50

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:04:50

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:04:50

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:04:50

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:04:50

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:04:50

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:04:50

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:04:50

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:04:50

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:04:50

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:04:50

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:04:50

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	23 Mar 2021 15:04:50

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 15:04:50

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Mar 2021 15:04:50

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Mar 2021 05:37:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 05:37:29
Data point term sent to Coder	System	23 Mar 2021 15:14:24
User entered 'Oxycodone'	(b) (4), (b) (6)	23 Mar 2021 15:13:36

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:13:36

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'Post appendectomy'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:13:36

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered '10'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:13:36

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:13:36

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:07

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:13:36

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:13:36

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:13:36

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:13:36

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:07

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:13:36

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered '3 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:13:36

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:13:36

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:13:36

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered '9 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:13:36

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:13:36

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:19
User entered empty.	System	23 Mar 2021 15:13:36

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:19
User entered empty.	System	23 Mar 2021 15:13:36

US3822181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:08:19
User entered empty.	System	23 Mar 2021 15:13:36

US3822181

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:56:07

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:13:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Mar 2021 12:49:33
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	03 Dec 2020 14:29:28

US3822181

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:56:07

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered '3 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 12:50:01

US3822181

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:56:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'Appendectomy'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 12:50:01

US3822181

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:56:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 12:50:01

US3822181

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:56:07

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 12:50:01

US3822181

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:56:07

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered '3 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:02:18

US3822181

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:56:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'CT Scan of Abdomen for appendicitis'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:02:18

US3822181

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:56:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:02:18

US3822181

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:56:07

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:02:18

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:06:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:22
User entered 'USA-US126-2021-MRNA-1273-P301000006'	System	05 Mar 2021 16:27:44

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 14:33:01
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:41:14
User entered 'Yes (Y)'	System	24 Mar 2021 17:40:39
Un-reviewed for Safety.	System	23 Mar 2021 15:07:35
DataPoint Un-verified.	System	23 Mar 2021 15:07:35
User entered 'No (N)'	System	23 Mar 2021 15:07:35
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 13:06:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:22
User entered 'Yes (Y)'	System	05 Mar 2021 16:27:44

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:06:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:22
User entered 'No (N)'	System	05 Mar 2021 16:27:44

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:06:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:22
User entered 'No (N)'	System	05 Mar 2021 16:27:44

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 14:33:25
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:41:14
User entered 'Yes (Y)'	System	24 Mar 2021 17:40:39
Un-reviewed for Safety.	System	23 Mar 2021 15:07:35
DataPoint Un-verified.	System	23 Mar 2021 15:07:35
User entered 'No (N)'	System	23 Mar 2021 15:07:35
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 13:06:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:22
User entered 'Yes (Y)'	System	05 Mar 2021 16:27:44

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:06:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:22
User entered 'No (N)'	System	05 Mar 2021 16:27:44

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:06:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:22
User entered 'No (N)'	System	05 Mar 2021 16:27:44

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:06:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:22
User entered 'No (N)'	System	05 Mar 2021 16:27:44

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:06:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:22
User entered 'Christina'	System	05 Mar 2021 16:27:44

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:06:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:22
User entered 'Kennelly'	System	05 Mar 2021 16:27:44

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:04:51
	(b) (4)	
User closed query 'Please complete address.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 14:33:53
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 14:33:39
	(b) (4), (b) (6)	
Query 'Please complete address.' answered with 'complete' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 17:24:47
Un-reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 17:24:21
	(b) (4), (b) (6)	
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 17:24:21
	(b) (4), (b) (6)	
User entered '6060 PIEDMONT ROW DRIVE SOUTH' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 17:24:21
User opened query 'Please complete address.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 16:57:37
User closed query 'Address fields incomplete.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 16:57:37
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 17:41:14
User entered empty.	System	24 Mar 2021 17:40:39
Query 'Address fields incomplete.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 15:25:11
	(b) (4), (b) (6)	
User entered '6060 PIEDMONT ROW DRIVE SOUTH' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 15:24:40
User opened query 'Address fields incomplete.' (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 17:21:30
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 17:21:30
User entered empty.	System	23 Mar 2021 15:07:35
Query 'Please complete all address fields.' answered with 'added' (Site from CRA).	Kelly Woodell (b) (4)	23 Mar 2021 13:41:37
	(b) (4)	
User entered '6060 Piedmont Row Drive South'	Kelly Woodell (b) (4)	23 Mar 2021 13:41:32
	(b) (4)	
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 13:07:25

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:04:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 14:33:39
Un-reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 17:24:21
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 17:24:21
User entered 'CHARLOTTE' reason for change:	(b) (4), (b) (6)	07 Apr 2021 17:24:21
Data Entry Error		
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 17:41:14
User entered empty.	System	24 Mar 2021 17:40:39
User entered 'CHARLOTTE' reason for change:	(b) (4), (b) (6)	24 Mar 2021 15:24:40
Data Entry Error		
User entered empty.	System	23 Mar 2021 15:07:35
User entered 'Charlotte'	Kelly Woodell (b) (4)	23 Mar 2021 13:41:32
	(b) (4)	

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:04:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 14:33:39
Un-reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 17:24:21
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 17:24:21
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 17:24:21
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 17:41:14
User entered empty.	System	24 Mar 2021 17:40:39
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 15:24:40
User entered empty.	System	23 Mar 2021 15:07:35
User entered 'NC'	Kelly Woodell (b) (4)	23 Mar 2021 13:41:32
	(b) (4)	

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:04:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 14:33:39
Un-reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 17:24:21
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 17:24:21
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 17:24:21
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 17:41:14
User entered empty.	System	24 Mar 2021 17:40:39
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 15:24:40
User entered empty.	System	23 Mar 2021 15:07:35
User entered '28210'	Kelly Woodell (b) (4)	23 Mar 2021 13:41:32
	(b) (4)	

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:41:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 13:06:55
User entered 'US'	System	05 Mar 2021 16:28:30

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Mar 2021 17:41:47
User entered '1'	System	05 Mar 2021 16:28:30

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:06:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:22
User entered 'USA-US126-2021-MRNA-1273-P301000006'	System	05 Mar 2021 16:27:44

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 14:33:01
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:41:14
User entered 'Yes (Y)'	System	24 Mar 2021 17:40:39
Un-reviewed for Safety.	System	23 Mar 2021 15:07:35
DataPoint Un-verified.	System	23 Mar 2021 15:07:35
User entered 'No (N)'	System	23 Mar 2021 15:07:35
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 13:06:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:22
User entered 'Yes (Y)'	System	05 Mar 2021 16:27:44

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:06:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:22
User entered 'No (N)'	System	05 Mar 2021 16:27:44

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:06:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:22
User entered 'No (N)'	System	05 Mar 2021 16:27:44

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 14:33:25
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:41:14
User entered 'Yes (Y)'	System	24 Mar 2021 17:40:39
Un-reviewed for Safety.	System	23 Mar 2021 15:07:35
DataPoint Un-verified.	System	23 Mar 2021 15:07:35
User entered 'No (N)'	System	23 Mar 2021 15:07:35
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 13:06:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:22
User entered 'Yes (Y)'	System	05 Mar 2021 16:27:44

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:06:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:22
User entered 'No (N)'	System	05 Mar 2021 16:27:44

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:06:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:22
User entered 'No (N)'	System	05 Mar 2021 16:27:44

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:06:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:22
User entered 'No (N)'	System	05 Mar 2021 16:27:44

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:06:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:22
User entered 'Christina'	System	05 Mar 2021 16:27:44

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:06:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:22
User entered 'Kennelly'	System	05 Mar 2021 16:27:44

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:04:51
User closed query 'Please complete address.' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 14:33:53
Query 'Please complete address.' answered with 'complete' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 14:33:39
Un-reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 17:24:47
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 17:24:21
User entered '6060 PIEDMONT ROW DRIVE SOUTH' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 17:24:21
User opened query 'Please complete address.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 16:57:37
User closed query 'Address fields incomplete.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 16:57:37
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
Reviewed for Safety.	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 17:41:14
Query 'Address fields incomplete.' answered with 'updated' (Site from CRA).	System	24 Mar 2021 17:40:39
User entered '6060 PIEDMONT ROW DRIVE SOUTH' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 15:25:11
User opened query 'Address fields incomplete.' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 15:24:40
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 17:21:30
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 17:21:30
Query 'Please complete all address fields.' answered with 'added' (Site from CRA).	System	23 Mar 2021 15:07:35
User entered '6060 Piedmont Row Drive South'	Kelly Woodell (b) (4)	23 Mar 2021 13:41:37
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 13:41:32
	(b) (4), (b) (6)	19 Mar 2021 13:07:25

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:04:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 14:33:39
Un-reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 17:24:21
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 17:24:21
User entered 'CHARLOTTE' reason for change:	(b) (4), (b) (6)	07 Apr 2021 17:24:21
Data Entry Error		
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 17:41:14
User entered empty.	System	24 Mar 2021 17:40:39
User entered 'CHARLOTTE' reason for change:	(b) (4), (b) (6)	24 Mar 2021 15:24:40
Data Entry Error		
User entered empty.	System	23 Mar 2021 15:07:35
User entered 'Charlotte'	Kelly Woodell (b) (4)	23 Mar 2021 13:41:32
	(b) (4)	

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:04:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 14:33:39
Un-reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 17:24:21
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 17:24:21
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 17:24:21
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 17:41:14
User entered empty.	System	24 Mar 2021 17:40:39
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 15:24:40
User entered empty.	System	23 Mar 2021 15:07:35
User entered 'NC'	Kelly Woodell (b) (4)	23 Mar 2021 13:41:32
	(b) (4)	

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:04:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 14:33:39
Un-reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 17:24:21
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 17:24:21
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 17:24:21
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 17:41:14
User entered empty.	System	24 Mar 2021 17:40:39
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 15:24:40
User entered empty.	System	23 Mar 2021 15:07:35
User entered '28210'	Kelly Woodell (b) (4)	23 Mar 2021 13:41:32
	(b) (4)	

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:41:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 13:06:55
User entered 'US'	System	05 Mar 2021 16:28:30

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Mar 2021 17:41:47
User entered '1'	System	05 Mar 2021 16:28:30

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:56:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:06:55
User entered '05/Mar/2021 10:28'	System	05 Mar 2021 16:28:30

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:56:07

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.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 17:41:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 13:06:55
User entered '1'	(b) (4), (b) (6)	05 Mar 2021 16:28:30

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:06:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:22
User entered 'USA-US126-2021-MRNA-1273-P301000006'	System	05 Mar 2021 16:27:44

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 14:33:01
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:41:14
User entered 'Yes (Y)'	System	24 Mar 2021 17:40:39
Un-reviewed for Safety.	System	23 Mar 2021 15:07:35
DataPoint Un-verified.	System	23 Mar 2021 15:07:35
User entered 'No (N)'	System	23 Mar 2021 15:07:35
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 13:06:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:22
User entered 'Yes (Y)'	System	05 Mar 2021 16:27:44

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:06:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:22
User entered 'No (N)'	System	05 Mar 2021 16:27:44

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:06:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:22
User entered 'No (N)'	System	05 Mar 2021 16:27:44

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 14:33:25
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:41:14
User entered 'Yes (Y)'	System	24 Mar 2021 17:40:39
Un-reviewed for Safety.	System	23 Mar 2021 15:07:35
DataPoint Un-verified.	System	23 Mar 2021 15:07:35
User entered 'No (N)'	System	23 Mar 2021 15:07:35
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 13:06:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:22
User entered 'Yes (Y)'	System	05 Mar 2021 16:27:44

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:06:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:22
User entered 'No (N)'	System	05 Mar 2021 16:27:44

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:06:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:22
User entered 'No (N)'	System	05 Mar 2021 16:27:44

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:06:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:22
User entered 'No (N)'	System	05 Mar 2021 16:27:44

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:06:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:22
User entered 'Christina'	System	05 Mar 2021 16:27:44

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:06:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:28:22
User entered 'Kennelly'	System	05 Mar 2021 16:27:44

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:04:51
User closed query 'Please complete address.' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 14:33:53
Query 'Please complete address.' answered with 'complete' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 14:33:39
Un-reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 17:24:47
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 17:24:21
User entered '6060 PIEDMONT ROW DRIVE SOUTH' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 17:24:21
User opened query 'Please complete address.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 16:57:37
User closed query 'Address fields incomplete.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 16:57:37
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
Reviewed for Safety.	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 17:41:14
Query 'Address fields incomplete.' answered with 'updated' (Site from CRA).	System	24 Mar 2021 17:40:39
User entered '6060 PIEDMONT ROW DRIVE SOUTH' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 15:25:11
User opened query 'Address fields incomplete.' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 15:24:40
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 17:21:30
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 17:21:30
Query 'Please complete all address fields.' answered with 'added' (Site from CRA).	System	23 Mar 2021 15:07:35
User entered '6060 Piedmont Row Drive South'	Kelly Woodell (b) (4)	23 Mar 2021 13:41:37
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 13:41:32
	(b) (4), (b) (6)	19 Mar 2021 13:07:25

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:04:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 14:33:39
Un-reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 17:24:21
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 17:24:21
User entered 'CHARLOTTE' reason for change:	(b) (4), (b) (6)	07 Apr 2021 17:24:21
Data Entry Error		
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 17:41:14
User entered empty.	System	24 Mar 2021 17:40:39
User entered 'CHARLOTTE' reason for change:	(b) (4), (b) (6)	24 Mar 2021 15:24:40
Data Entry Error		
User entered empty.	System	23 Mar 2021 15:07:35
User entered 'Charlotte'	Kelly Woodell (b) (4)	23 Mar 2021 13:41:32
	(b) (4)	

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:04:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 14:33:39
Un-reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 17:24:21
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 17:24:21
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 17:24:21
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 17:41:14
User entered empty.	System	24 Mar 2021 17:40:39
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 15:24:40
User entered empty.	System	23 Mar 2021 15:07:35
User entered 'NC'	Kelly Woodell (b) (4)	23 Mar 2021 13:41:32
	(b) (4)	

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:04:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 14:33:39
Un-reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 17:24:21
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 17:24:21
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 17:24:21
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 17:41:14
User entered empty.	System	24 Mar 2021 17:40:39
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 15:24:40
User entered empty.	System	23 Mar 2021 15:07:35
User entered '28210'	Kelly Woodell (b) (4)	23 Mar 2021 13:41:32
	(b) (4)	

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Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:41:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 13:06:55
User entered 'US'	System	05 Mar 2021 16:28:30

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Mar 2021 17:41:47
User entered '1'	System	05 Mar 2021 16:28:30

US3822181

Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:56:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 14:33:39
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered '24/Mar/2021 13:41'	(b) (4) System	24 Mar 2021 17:41:47

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Folder: SAE USA-US126-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:56:07

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)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 14:33:39
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:10:48
User entered '1'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:41:47